Australian Government

Department of Health, Disability and Ageing

PBS

# Schedule of Pharmaceutical Benefits

General Pharmaceutical Benefits

**Effective 1 November 2026**

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This Schedule provides information on the arrangements for the prescribing and supply of pharmaceutical benefits. These arrangements operate under the *National Health Act 1953*. However, at the time of printing, the relevant legislation giving authority for the changes included in this issue of the Schedule may still be subject to the usual Parliamentary scrutiny. This book is not a legal document, and, in cases of discrepancy, the legislation will be the source document for payment for the supply of pharmaceutical benefits. The legislation is available from the Federal Register of Legislation website at www.legislation.gov.au.

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# Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply from 1 November 2026 and are included, where applicable, in prices published in the Schedule.

| | | |
|---|---|---|
| Dispensing Fees: | Ready-prepared | $9.24 |
| | Dangerous drug fee | $5.73 |
| | Extemporaneously-prepared | $11.28 |
| | Allowable additional patient charge* | $2.79 |
| Additional Fees (for safety net prices): | Ready-prepared | $1.54 |
| | Extemporaneously-prepared | $1.99 |
| Patient Co-payments: | General | $25.00 |
| | Concessional | $7.70 |
| Safety Net Thresholds: | General | $1748.20 |
| | Concessional | $277.20 |
| Safety Net Card Issue Fee: | | $12.78 |

* The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the Safety Net threshold.

# Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 November 2026. The Schedule is updated on the first day of each month and is also available at www.pbs.gov.au.

## General Pharmaceutical Benefits

### Additions

***Addition – Item***

14726C **ACARBOSE**, acarbose 50 mg tablet, 90 *(Acarbose 50 mg tablets (Morningside Healthcare, UK))*

14735M **ACARBOSE**, acarbose 50 mg tablet, 90 *(Acarbose 50 mg tablets (Morningside Healthcare, UK))*

14722W **ACARBOSE**, acarbose 100 mg tablet, 90 *(Acarbose 100 mg tablets (Morningside Healthcare, UK))*

14734L **ACARBOSE**, acarbose 100 mg tablet, 90 *(Acarbose 100 mg tablets (Morningside Healthcare, UK))*

15548H **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15550K **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15557T **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15558W **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15563D **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15564E **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15565F **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15566G **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15567H **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15572N **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15573P **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15575R **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15583E **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15584F **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15590M **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15591N **ADALIMUMAB**, Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe *(Amgevita)*

15560Y **ALBENDAZOLE**, albendazole 400 mg tablet, 60 *(Albendazole (Micro Labs, Germany))*

15592P **EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL pen device *(Repatha)*

15599B **EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL pen device *(Repatha)*

13821K **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules *(PMS-SALBUTAMOL (Canada))*

***Addition – Brand***

2698B *ABURA, VM* – **ABIRATERONE**, abiraterone acetate 250 mg tablet, 120

11206T *ABURA, VM* – **ABIRATERONE**, abiraterone acetate 500 mg tablet, 60

12340L *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12342N *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12345R *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12347W *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12358K *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12362P *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12363Q *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12373F *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12375H *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12376J *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12377K *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12381P *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12383R *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12389C *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12390D *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12411F *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12412G *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12414J *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12425Y *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12428D *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12429E *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12432H *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12433J *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12446C *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12454L *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13211H *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13214L *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13215M *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13221W *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13223Y *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13224B *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13225C *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13226D *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13227E *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13230H *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13691N *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13703F *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13764K *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

14221L *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

14234E *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

14242N *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

14272E *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

14973C *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

15031D *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

15038L *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

15146E *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

15153M *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

15159W *Amgevita, AN* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12360M *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12374G *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12419P *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12426B *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12447D *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12448E *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12449F *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12450G *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

14587R *Amgevita, AN* – **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

1354G *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 20 mg tablet, 60

9125G *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 20 mg tablet, 60

12869H *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 20 mg tablet, 60

1381Q *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 50 mg tablet, 60

9126H *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 50 mg tablet, 60

12843Y *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 50 mg tablet, 60

1415L *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 70 mg tablet, 60

9127J *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 70 mg tablet, 60

12890K *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 70 mg tablet, 60

1416M *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 100 mg tablet, 30

9343R *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 100 mg tablet, 30

12889J *MSN Dasatinib, VM* – **DASATINIB**, dasatinib 100 mg tablet, 30

8879H *Eplerenone Viatris, AL* – **EPLERENONE**, eplerenone 25 mg tablet, 30

13590G *Eplerenone Viatris, AL* – **EPLERENONE**, eplerenone 25 mg tablet, 30

8757X *Ezetimibe Viatris, MQ* – **EZETIMIBE**, ezetimibe 10 mg tablet, 30

13440J *Ezetimibe Viatris, MQ* – **EZETIMIBE**, ezetimibe 10 mg tablet, 30

3439B *Diaformin Viatris XR, VY* – **METFORMIN**, metformin hydrochloride 1 g modified release tablet, 60

13847T *Diaformin Viatris XR, VY* – **METFORMIN**, metformin hydrochloride 1 g modified release tablet, 60

1692C *Fudantin, NB* – **NITROFURANTOIN**, nitrofurantoin 50 mg capsule, 30

1693D *Fudantin, NB* – **NITROFURANTOIN**, nitrofurantoin 100 mg capsule, 30

8224W *Ondansetron VTRS, AF* – **ONDANSETRON**, ondansetron 4 mg tablet, 4

12192Q *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 2.5 mg tablet, 60

12197Y *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 2.5 mg tablet, 60

13366L *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 2.5 mg tablet, 60

9467G *Blooms The Chemist Rivaroxaban, BG* – **RIVAROXABAN**, rivaroxaban 10 mg tablet, 30

11633G *Blooms The Chemist Rivaroxaban, BG* – **RIVAROXABAN**, rivaroxaban 10 mg tablet, 30

13521P *Blooms The Chemist Rivaroxaban, BG* – **RIVAROXABAN**, rivaroxaban 10 mg tablet, 30

2691P *Blooms The Chemist Rivaroxaban, BG* – **RIVAROXABAN**, rivaroxaban 15 mg tablet, 28

13463N *Blooms The Chemist Rivaroxaban, BG* – **RIVAROXABAN**, rivaroxaban 15 mg tablet, 28

2160Q *Blooms The Chemist Rivaroxaban, BG* – **RIVAROXABAN**, rivaroxaban 15 mg tablet, 42

2268J *Blooms The Chemist Rivaroxaban, BG* – **RIVAROXABAN**, rivaroxaban 20 mg tablet, 28

13462M *Blooms The Chemist Rivaroxaban, BG* – **RIVAROXABAN**, rivaroxaban 20 mg tablet, 28

11123K *MSN-SACUBITRIL/VALSARTAN, VM* – **SACUBITRIL + VALSARTAN**, sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56

13570F *MSN-SACUBITRIL/VALSARTAN, VM* – **SACUBITRIL + VALSARTAN**, sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56

11131W *MSN-SACUBITRIL/VALSARTAN, VM* – **SACUBITRIL + VALSARTAN**, sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56

13511D *MSN-SACUBITRIL/VALSARTAN, VM* – **SACUBITRIL + VALSARTAN**, sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56

11122J *MSN-SACUBITRIL/VALSARTAN, VM* – **SACUBITRIL + VALSARTAN**, sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56

13445P *MSN-SACUBITRIL/VALSARTAN, VM* – **SACUBITRIL + VALSARTAN**, sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56

2142R *Sevelamer Waymade, IX* – **SEVELAMER**, sevelamer hydrochloride 800 mg tablet, 180

13934J *Sevelamer Waymade, IX* – **SEVELAMER**, sevelamer hydrochloride 800 mg tablet, 180

10090C *ARX-Sitagliptin/Metformin XR 50/1000, XT* – **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56

13990H *ARX-Sitagliptin/Metformin XR 50/1000, XT* – **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56

10089B *ARX-Sitagliptin/Metformin XR 100/1000, XT* – **SITAGLIPTIN + METFORMIN**, sitagliptin 100 mg + metformin hydrochloride 1 g modified release tablet, 28

14031L *ARX-Sitagliptin/Metformin XR 100/1000, XT* – **SITAGLIPTIN + METFORMIN**, sitagliptin 100 mg + metformin hydrochloride 1 g modified release tablet, 28

2180R *ARX-TRANEXAMIC ACID, XT* – **TRANEXAMIC ACID**, tranexamic acid 500 mg tablet, 100

### *Addition – Equivalence Indicator*

8459F *Eskazole, AS* – **ALBENDAZOLE**, albendazole 400 mg tablet, 60

11130T *Ventolin Nebules, GK* – **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

### *Addition – Note*

13955L **ACARBOSE**, acarbose 50 mg tablet, 90 *(Acarbose Viatris, GLYBOSAY)*

8189B **ACARBOSE**, acarbose 100 mg tablet, 90 *(Acarbose Viatris, GLYBOSAY)*

13869Y **ACARBOSE**, acarbose 100 mg tablet, 90 *(Acarbose Viatris, GLYBOSAY)*

8459F **ALBENDAZOLE**, albendazole 400 mg tablet, 60 *(Eskazole)*

11130T **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules *(Ventolin Nebules)*

## Deletions

### *Deletion – Item*

13110B **GLATIRAMER ACETATE**, glatiramer acetate 40 mg/mL injection, 12 x 1 mL pen devices *(Copaxone)*

14793N **PRAZOSIN**, prazosin 1 mg capsule, 100 *(Prazosin Hydrochloride Capsules, USP 1 mg (Novitium Pharma, USA))*

14834R **PRAZOSIN**, prazosin 1 mg capsule, 100 *(Prazosin Hydrochloride Capsules, USP 1 mg (Novitium Pharma, USA))*

### *Deletion – Brand*

8720Y *ARIPIPRAZOLE-WGR, WG* – **ARIPIPRAZOLE**, aripiprazole 30 mg tablet, 30

8888T *Mobic, BY* – **MELOXICAM**, meloxicam 15 mg capsule, 30

3381Y *OLANZAPINE ODT-WGR, WG* – **OLANZAPINE**, olanzapine 5 mg orally disintegrating tablet, 28

3384D *OLANZAPINE ODT-WGR, WG* – **OLANZAPINE**, olanzapine 15 mg orally disintegrating tablet, 28

### *Deletion – Note*

10416F **GLATIRAMER ACETATE**, glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes *(Copaxone, Glatira)*

15064W **IPTACOPAN**, Iptacopan 200 mg capsule, 56 *(Fabhalta)*

1479W **PRAZOSIN**, prazosin 1 mg tablet, 100 *(APO-Prazosin, Minipress)*

13553H **PRAZOSIN**, prazosin 1 mg tablet, 100 *(APO-Prazosin, Minipress)*

***Deletion – Restriction***

15064W **IPTACOPAN**, Iptacopan 200 mg capsule, 56 *(Fabhalta)*

## Supply Only

***Supply Only – Period Commencing***

15084X **ELAFIBRANOR**, Elafibranor 80 mg tablet, 30 *(Iqirvo)*

***Supply Only – Period Ending***

8200N **AZITHROMYCIN**, azithromycin 500 mg tablet, 2 *(APO-Azithromycin, Azithromycin Sandoz, Azithromycin Viatris, AZITHROMYCIN-WGR, ZITHRO, Zithromax)*

9031H **MICONAZOLE**, miconazole 2% solution, 30 mL *(Daktarin Tincture)*

## Advance Notices

***1 December 2026***

***Deletion – Item***

8678R *Phlexy-10, SB* – **AMINO ACID FORMULA WITHOUT PHENYLALANINE**, amino acid formula without phenylalanine 1 g tablet, 75

8746H *Easiphen, SB* – **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE**, amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL

15071F *Darzalex SC, JC* – **DARATUMUMAB**, daratumumab 1.8 g/15 mL injection, 15 mL vial

5491B *Teveten, GO* – **EPROSARTAN**, eprosartan 600 mg tablet, 28

8447N *Teveten, GO* – **EPROSARTAN**, eprosartan 600 mg tablet, 28

13861M *Teveten, GO* – **EPROSARTAN**, eprosartan 600 mg tablet, 28

13912F *Teveten, GO* – **EPROSARTAN**, eprosartan 600 mg tablet, 28

8624X *Teveten Plus 600/12.5, GO* – **EPROSARTAN + HYDROCHLOROTHIAZIDE**, eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28

14337N *Teveten Plus 600/12.5, GO* – **EPROSARTAN + HYDROCHLOROTHIAZIDE**, eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28

2939Q *Daonil, SW* – **GLIBENCLAMIDE**, glibenclamide 5 mg tablet, 100

13868X *Daonil, SW* – **GLIBENCLAMIDE**, glibenclamide 5 mg tablet, 100

11844J *PKU GMPro LQ, SB* – **GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE**, glycomacropeptide formula with docosahexaenoic acid and low phenylalanine oral liquid, 18 x 250 mL cartons

12911M *Imatab, JU* – **IMATINIB**, imatinib 600 mg tablet, 30

12912N *Imatab, JU* – **IMATINIB**, imatinib 600 mg tablet, 30

12919Y *Imatab, JU* – **IMATINIB**, imatinib 600 mg tablet, 30

12920B *Imatab, JU* – **IMATINIB**, imatinib 600 mg tablet, 30

12923E *Imatab, JU* – **IMATINIB**, imatinib 600 mg tablet, 30

12926H *Imatab, JU* – **IMATINIB**, imatinib 600 mg tablet, 30

12927J *Imatab, JU* – **IMATINIB**, imatinib 600 mg tablet, 30

12935T *Imatab, JU* – **IMATINIB**, imatinib 600 mg tablet, 30

1166J *Amdipharm Mercury (Australia) Pty Limited, GH* – **PHENOXYBENZAMINE**, phenoxybenzamine hydrochloride 10 mg capsule, 30

1034K *Bricanyl, AP* – **TERBUTALINE**, terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules

***Deletion – Brand***

2698B *Zytiga, JC* – **ABIRATERONE**, abiraterone acetate 250 mg tablet, 120

11206T *Zytiga, JC* – **ABIRATERONE**, abiraterone acetate 500 mg tablet, 60

1886G *Amoxil, AS* – **AMOXICILLIN**, amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL

3302T *Amoxil, AS* – **AMOXICILLIN**, amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL

8508T *Rabeprazole Mylan, AF* – **RABEPRAZOLE**, rabeprazole sodium 20 mg enteric tablet, 30

8509W *Rabeprazole Mylan, AF* – **RABEPRAZOLE**, rabeprazole sodium 20 mg enteric tablet, 30

11670F *Rabeprazole Mylan, AF* – **RABEPRAZOLE**, rabeprazole sodium 20 mg enteric tablet, 30

12286P *Rabeprazole Mylan, AF* – **RABEPRAZOLE**, rabeprazole sodium 20 mg enteric tablet, 30

14396Q *Rabeprazole Mylan, AF* – **RABEPRAZOLE**, rabeprazole sodium 20 mg enteric tablet, 30

14433P *Rabeprazole Mylan, AF* – **RABEPRAZOLE**, rabeprazole sodium 20 mg enteric tablet, 30

14463F *Rabeprazole Mylan, AF* – **RABEPRAZOLE**, rabeprazole sodium 20 mg enteric tablet, 30

11856B *Sevelamer Lupin, GQ* – **SEVELAMER**, sevelamer carbonate 800 mg tablet, 180

14027G *Sevelamer Lupin, GQ* – **SEVELAMER**, sevelamer carbonate 800 mg tablet, 180

3113W *VANCOR, CR* – **VANCOMYCIN**, vancomycin 125 mg capsule, 20

3114X *VANCOR, CR* – **VANCOMYCIN**, vancomycin 250 mg capsule, 20

### *1 January 2027*

#### *Deletion – Item*

11937G *Braftovi, FB* – **ENCORAFENIB**, encorafenib 50 mg capsule, 28

11954E *Braftovi, FB* – **ENCORAFENIB**, encorafenib 50 mg capsule, 28

9040T *Levemir Penfill, NO* – **INSULIN DETEMIR**, insulin detemir 100 units/mL injection, 5 x 3 mL cartridges

12236B *Levemir FlexPen, NF* – **INSULIN DETEMIR**, insulin detemir 100 units/mL injection, 5 x 3 mL pen devices

#### *Deletion – Brand*

2518M *Aprepitant APOTEX, TX* – **APREPITANT**, aprepitant 165 mg capsule, 1

1775K *BenPen, SZ* – **BENZYLPENICILLIN**, benzylpenicillin 600 mg injection, 1 vial

3398W *BenPen, SZ* – **BENZYLPENICILLIN**, benzylpenicillin 600 mg injection, 1 vial

8094B *Calutex, AS* – **BICALUTAMIDE**, bicalutamide 50 mg tablet, 28

8480H *Vasocardol CD, AV* – **DILTIAZEM**, diltiazem hydrochloride 360 mg modified release capsule, 30

14565N *Vasocardol CD, AV* – **DILTIAZEM**, diltiazem hydrochloride 360 mg modified release capsule, 30

1761Q *Protaphane Penfill 3 mL, NO* – **INSULIN ISOPHANE HUMAN**, insulin isophane human 100 units/mL injection, 5 x 3 mL cartridges

1762R *Actrapid Penfill 3 mL, NO* – **INSULIN NEUTRAL HUMAN**, insulin neutral human 100 units/mL injection, 5 x 3 mL cartridges

2237R *Sertraline generichealth, GQ* – **SERTRALINE**, sertraline 100 mg tablet, 30

8837D *Sertraline generichealth, GQ* – **SERTRALINE**, sertraline 100 mg tablet, 30

14404D *Sertraline generichealth, GQ* – **SERTRALINE**, sertraline 100 mg tablet, 30

14506L *Sertraline generichealth, GQ* – **SERTRALINE**, sertraline 100 mg tablet, 30

### *1 February 2027*

#### *Deletion – Brand*

8887R *Mobic, BY* – **MELOXICAM**, meloxicam 7.5 mg capsule, 30

1215Y *Paracetamol/Codeine GH 500/30, GQ* – **PARACETAMOL + CODEINE**, paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

3316M *Paracetamol/Codeine GH 500/30, GQ* – **PARACETAMOL + CODEINE**, paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

12022R *Paracetamol/Codeine GH 500/30, GQ* – **PARACETAMOL + CODEINE**, paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

12066C *Paracetamol/Codeine GH 500/30, GQ* – **PARACETAMOL + CODEINE**, paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

# About the Schedule

The Schedule of Pharmaceutical Benefits lists all ready-prepared items subsidised under the Pharmaceutical Benefits Scheme (PBS).

The Schedule is published and is effective on the first day of each month.

For detailed information about the prescribing and supply of pharmaceutical benefits go to www.pbs.gov.au

For information about the operational aspects of the PBS, such as, PBS claiming, authority applications and stationery supplies contact Services Australia at www.servicesaustralia.gov.au

## Symbols and Abbreviations Used in the Schedule

| | |
|---|---|
| * | An asterisk in the dispensed price column indicates that the manufacturer's pack does not coincide with the maximum quantity |
| ‡ | A double dagger in the maximum quantity column indicates where the maximum quantity has been determined to match the manufacturer's pack. These packs cannot be broken and the maximum quantity should be supplied and claimed |
| # | A gauge in the dispensed price column indicates that the product is not preconstituted and that the dispensed price therefore included a dispensing fee and where appropriate, an amount for purified water |
| a or b | Located immediately before brand names of an item indicates that the brands are equivalent for the purposes of substitution. These brands may be interchanged without differences in clinical effect |
| B | Located immediately before an amount in the premium column indicates a brand premium which applies to that particular brand of the item |
| T | Located immediately before an amount in the premium column indicates a therapeutic group premium which applies to that particular item |
| S | Located immediately before an amount in the premium column indicates a special patient contribution which applies to that particular item |
| DPMQ $ | Dispensed price for maximum quantity |
| MRVSN $ | Maximum recordable value for safety net |
| NP | Indicates that the item can be prescribed by an authorised nurse practitioner |
| MW | Indicates that the item can be prescribed by an authorised midwife |
| OP | Indicates that the item can be prescribed by an authorised optometrist |
| DP | Indicates that the item can be prescribed by an authorised dental practitioner |

# Restricted Benefits

All restricted items have separate headings for authority and non-authority items. In each case these items may be prescribed as pharmaceutical benefits only for use for one of the specified indications. Where more than one indication is specified for an Authority required or Restricted pharmaceutical benefit, each indication is separated from the preceding indication by a semi-colon and commences on the next line. In the case of Authority required (STREAMLINED) items, each restriction will also include a streamlined authority code. The drug may be prescribed as a pharmaceutical benefit for a patient who qualifies under any of the specified indications.

Restricted benefits – above an item indicates where an item can only be prescribed for specific therapeutic uses.

Authority required benefits – above an item indicates that a prescriber must seek approval from Services Australia or the Department of Veterans' Affairs. The prescriber must declare the specific conditions and circumstances that justify the use of these medicines. This is usually done by phone or in writing.

Authority required (STREAMLINED) – authority can be sought electronically.

# General Statements

## General Statement for Drugs for the Treatment of Hepatitis C

Use the following criteria to determine patient eligibility for subsidisation under the PBS for hepatitis C treating agents.

By writing a PBS prescription, the prescriber is certifying the patient satisfies the qualifying criteria set out below and the use in accordance with the registered indications which differ between agents in this class – refer to the current Product Information for details.

**Treatment criteria:**

Must be treated by a medical practitioner or an authorised nurse practitioner experienced in the treatment of chronic hepatitis C infection; or in consultation with a gastroenterologist, hepatologist or infectious diseases physician experienced in the treatment of chronic hepatitis C infection.

The following information must be provided at the time of application:

- the patient's cirrhotic status (non-cirrhotic or cirrhotic)
- details of the previous treatment regimen (only for requests for sofosbuvir + velpatasvir + voxilaprevir (Vosevi®) or glecaprevir + pibrentasvir (Maviret®) for 16 weeks' treatment in patients who have previously failed a treatment with a regimen containing an NS5A inhibitor).

The following information must be documented in the patient's medical records:

a) evidence of chronic hepatitis C infection:

- antibody to hepatitis C virus (anti-HCV) positive; and
- repeated hepatitis C virus ribonucleic acid (HCV RNA) positive; and

b) evidence of the hepatitis C virus genotype (where possible)

The following matrices identify the regimens which are available for PBS prescription for eligible patients, based on the hepatitis C virus genotype and treatment history.

***HEPATITIS C - NON-CIRRHOTIC PATIENTS***

| | TREATMENT NAÏVE | TREATMENT EXPERIENCED |
|---|---|---|
| **All genotypes** (Pan-genotypic regimens) | **SOFOSBUVIR** + **VELPATASVIR**<br>[12 weeks]<br>OR<br>**GLECAPREVIR** + **PIBRENTASVIR**<br>[8 weeks] | **SOFOSBUVIR** + **VELPATASVIR**<br>[12 weeks]<br>OR<br>**SOFOSBUVIR** + **VELPATASVIR** + **VOXILAPREVIR**<br>[12 weeks] [1]<br>OR<br>**GLECAPREVIR** + **PIBRENTASVIR**<br>[8 or 12 or 16 weeks] [2] |

***HEPATITIS C – CIRRHOTIC PATIENTS***

| | TREATMENT NAÏVE | TREATMENT EXPERIENCED |
|---|---|---|
| **All genotypes** (Pan-genotypic regimens) | **SOFOSBUVIR** + **VELPATASVIR** [12 weeks] [3, 4]<br>OR<br>**GLECAPREVIR + PIBRENTASVIR**<br>[12 weeks] [5] | **SOFOSBUVIR** + **VELPATASVIR** [12 weeks] [3, 4]<br>OR<br>**SOFOSBUVIR** + **VELPATASVIR** + **VOXILAPREVIR**<br>[12 weeks] [1]<br>OR<br>**GLECAPREVIR + PIBRENTASVIR** [12 or 16 weeks] [6] |

1. SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] only for patients who have failed an NS5A inhibitor.
2. GLECAPREVIR + PIBRENTASVIR [8 or 12 or 16 weeks] for non-cirrhotic patients:
   - treatment for 8 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;

- treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
- treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
- treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.

[3.] SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with decompensated cirrhosis. Use in combination with ribavirin.
[4.] SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with genotype 3 infection with compensated cirrhosis. Consider addition of ribavirin.
[5.] GLECAPREVIR + PIBRENTASVIR – A treatment duration of 12 weeks may be considered for patients with compensated cirrhosis, at the discretion of the prescriber.
[6.] GLECAPREVIR + PIBRENTASVIR [12 or 16 weeks] for cirrhotic patients:

- treatment for 12 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
- treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
- treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
- treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.

# General Pharmaceutical Benefits


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# ALIMENTARY TRACT AND METABOLISM

## STOMATOLOGICAL PREPARATIONS

### STOMATOLOGICAL PREPARATIONS

#### *Antiinfectives and antiseptics for local oral treatment*

### AMPHOTERICIN B

**amphotericin B 10 mg lozenge, 20**

| 2931G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 18.56 | 20.10 | Fungilin [AS] |

**amphotericin B 10 mg lozenge, 20**

| 3306B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 18.56 | 20.10 | Fungilin [AS] |

#### *Other agents for local oral treatment*

### BENZYDAMINE

**Restricted benefit**

***5672***

Mucositis

**Clinical criteria:**

- The condition must be radiation induced.

**benzydamine hydrochloride 0.15% mouthwash, 500 mL**

| 1121B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 22.81 | 24.35 | Difflam [IL] |

### BENZYDAMINE

**Restricted benefit**

***5732***

Mucositis

**Clinical criteria:**

- The condition must be radiation induced.

**benzydamine hydrochloride 0.15% mouthwash, 500 mL**

| 5032W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 22.81 | 24.35 | Difflam [IL] |

## DRUGS FOR ACID RELATED DISORDERS

### DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)

#### *H2-receptor antagonists*

### FAMOTIDINE

**Note** *Helicobacter pylori* eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

**famotidine 20 mg tablet, 60**

| 2487X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.18 | 19.72 | Ausfam 20 [RW] |

**famotidine 40 mg tablet, 30**

| 2488Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.18 | 19.72 | Ausfam 40 [RW] |

### FAMOTIDINE

**Note** *Helicobacter pylori* eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**famotidine 20 mg tablet, 60**

| 15047Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.00 | 23.54 | Ausfam 20 [RW] |

**famotidine 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15061Q NP | 2 | 5 | 0.00 | *22.00 | 23.54 | Ausfam 40 [RW] |

## NIZATIDINE

**Note** *Helicobacter pylori* eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

**nizatidine 150 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1505F NP | 1 | 5 | 0.00 | 24.49 | 25.00 | [a] Nizac [RF] | [a] Tacidine [AF] |
| | | | [B]7.36 | 31.85 | 25.00 | [a] Tazac [RW] | |

**nizatidine 300 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1504E NP | 1 | 5 | 0.00 | 24.49 | 25.00 | [a] Nizac [RF] | [a] Tacidine [AF] |
| | | | [B]7.36 | 31.85 | 25.00 | [a] Tazac [RW] | |

## NIZATIDINE

**Note** *Helicobacter pylori* eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**nizatidine 150 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14306Y NP | 2 | 5 | 0.00 | *34.62 | 25.00 | [a] Nizac [RF] | [a] Tacidine [AF] |
| | | | [B]14.72 | *49.34 | 25.00 | [a] Tazac [RW] | |

**nizatidine 300 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14372K NP | 2 | 5 | 0.00 | *34.62 | 25.00 | [a] Nizac [RF] | [a] Tacidine [AF] |
| | | | [B]14.72 | *49.34 | 25.00 | [a] Tazac [RW] | |

## RANITIDINE

**Note** *Helicobacter pylori* eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

**ranitidine 150 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1978D NP MW | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APO-Ranitidine [TX] | [a] Zantac 150 [AS] |

**ranitidine 300 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1977C NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APO-Ranitidine [TX] | [a] Zantac 300 [AS] |

### *Proton pump inhibitors*

## ESOMEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Standard dose proton pump inhibitors are appropriate step-down therapy from high dose proton pump inhibitors.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

**Authority Required**

***16555***

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Clinical criteria:**

- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**Authority Required**

***16634***

Scleroderma oesophagus

**Clinical criteria:**

- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**esomeprazole 40 mg enteric tablet, 30**

| 3401B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.44 | 22.98 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole GH [GQ] |
| | | | | | | [a] Esomeprazole GxP [AF] | [a] Esomeprazole RBX [RA] |
| | | | | | | [a] Esomeprazole Viatris [MQ] | [a] ESOMEPRAZOLE-WGR [WG] |
| | | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | | [a] Nexole [RF] | |
| | | | [B]6.79 | 28.23 | 22.98 | [a] Nexium [AP] | |

**esomeprazole 40 mg enteric capsule, 30**

| 10331R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.44 | 22.98 | [a] Noxicid Caps [AL] |

## ESOMEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Standard dose proton pump inhibitors are appropriate step-down therapy from high dose proton pump inhibitors.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

**Authority Required**

***16659***

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**Authority Required**

***16489***

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**esomeprazole 40 mg enteric tablet, 30**

| 14373L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *28.52 | 25.00 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole GH [GQ] |
| | | | | | | [a] Esomeprazole GxP [AF] | [a] Esomeprazole RBX [RA] |
| | | | | | | [a] Esomeprazole Viatris [MQ] | [a] ESOMEPRAZOLE-WGR [WG] |
| | | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | | [a] Nexole [RF] | |
| | | | [B]13.58 | 42.10 | 25.00 | [a] Nexium [AP] | |

**esomeprazole 40 mg enteric capsule, 30**

| 14405E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *28.52 | 25.00 | [a] Noxicid Caps [AL] |

## ESOMEPRAZOLE

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Standard dose proton pump inhibitors are appropriate step-down therapy from high dose proton pump inhibitors.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***8902***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

### esomeprazole 40 mg enteric tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8601Q | | | | | | | |
| NP | 1 | 1 | 0.00 | 21.44 | 22.98 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole GH [GQ] |
| | | | | | | [a] Esomeprazole GxP [AF] | [a] Esomeprazole RBX [RA] |
| | | | | | | [a] Esomeprazole Viatris [MQ] | [a] ESOMEPRAZOLE-WGR [WG] |
| | | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | | [a] Nexole [RF] | |
| | | | [B]6.79 | 28.23 | 22.98 | [a] Nexium [AP] | |

### esomeprazole 40 mg enteric capsule, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10330Q | | | | | | |
| NP | 1 | 1 | 0.00 | 21.44 | 22.98 | [a] Noxicid Caps [AL] |

## ESOMEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***8775***

Peptic ulcer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have tested negative for helicobacter pylori infection; **OR**
- Patient must have failed treatment with helicobacter pylori eradication therapy.

### esomeprazole 20 mg enteric tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8886Q | | | | | | | |
| NP | 1 | 1 | 0.00 | 18.60 | 20.14 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole GH [GQ] |
| | | | | | | [a] Esomeprazole GxP [AF] | [a] Esomeprazole RBX [RA] |
| | | | | | | [a] Esomeprazole Viatris [MQ] | [a] ESOMEPRAZOLE-WGR [WG] |
| | | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | | [a] Nexole [RF] | |
| | | | [B]6.72 | 25.32 | 20.14 | [a] Nexium [AP] | |

### esomeprazole 20 mg enteric capsule, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10295W | | | | | | |
| NP | 1 | 1 | 0.00 | 18.60 | 20.14 | [a] Noxicid Caps [AL] |

## ESOMEPRAZOLE

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***8776***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**esomeprazole 20 mg enteric capsule, 30**

| 11687D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] Noxicid Caps [AL] |

**esomeprazole 20 mg enteric tablet, 30**

| 11692J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole GH [GQ] |
| | | | | | | [a] Esomeprazole GxP [AF] | [a] Esomeprazole RBX [RA] |
| | | | | | | [a] Esomeprazole Viatris [MQ] | [a] ESOMEPRAZOLE-WGR [WG] |
| | | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | | [a] Nexole [RF] | |
| | | | [B]6.72 | 25.32 | 20.14 | [a] Nexium [AP] | |

## ESOMEPRAZOLE

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15530***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**esomeprazole 20 mg enteric capsule, 30**

| 14303T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] Noxicid Caps [AL] |

**esomeprazole 20 mg enteric tablet, 30**

| 14444F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole GH [GQ] |
| | | | | | | [a] Esomeprazole GxP [AF] | [a] Esomeprazole RBX [RA] |
| | | | | | | [a] Esomeprazole Viatris [MQ] | [a] ESOMEPRAZOLE-WGR [WG] |
| | | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | | [a] Nexole [RF] | |
| | | | [B]13.44 | 36.28 | 24.38 | [a] Nexium [AP] | |

## ESOMEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***8774***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; **OR**
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

**esomeprazole 20 mg enteric tablet, 30**

| 14692G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 18.60 | 20.14 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole GH [GQ] |
| | | | | | | [a] Esomeprazole GxP [AF] | [a] Esomeprazole RBX [RA] |
| | | | | | | [a] Esomeprazole Viatris [MQ] | [a] ESOMEPRAZOLE-WGR [WG] |
| | | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | | [a] Nexole [RF] | |
| | | | [B]6.72 | 25.32 | 20.14 | [a] Nexium [AP] | |

**esomeprazole 20 mg enteric capsule, 30**

| 14701R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 18.60 | 20.14 | [a] Noxicid Caps [AL] |

## ESOMEPRAZOLE

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required (STREAMLINED)**

***8780***

Scleroderma oesophagus

**Authority Required (STREAMLINED)**

***8827***

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**esomeprazole 20 mg enteric tablet, 30**

| 8600P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole GH [GQ] |
| | | | | | | [a] Esomeprazole GxP [AF] | [a] Esomeprazole RBX [RA] |
| | | | | | | [a] Esomeprazole Viatris [MQ] | [a] ESOMEPRAZOLE-WGR [WG] |
| | | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | | [a] Nexole [RF] | |
| | | | [B]6.72 | 25.32 | 20.14 | [a] Nexium [AP] | |

**esomeprazole 20 mg enteric capsule, 30**

| 10343J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] Noxicid Caps [AL] |

## ESOMEPRAZOLE

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required (STREAMLINED)**

***15658***

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required (STREAMLINED)**

***15682***

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**esomeprazole 20 mg enteric tablet, 30**

| 14308C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole GH [GQ] |
| | | | | | | [a] Esomeprazole GxP [AF] | [a] Esomeprazole RBX [RA] |
| | | | | | | [a] Esomeprazole Viatris [MQ] | [a] ESOMEPRAZOLE-WGR [WG] |
| | | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | | [a] Nexole [RF] | |
| | | | [B]13.44 | 36.28 | 24.38 | [a] Nexium [AP] | |

**esomeprazole 20 mg enteric capsule, 30**

| 14510Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] Noxicid Caps [AL] |

## ESOMEPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of *Helicobacter pylori.*

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***11310***

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; **OR**
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; **OR**
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; **OR**
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; **OR**
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**esomeprazole 20 mg enteric capsule, 30**

| 12275C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] Noxicid Caps [AL] |

**esomeprazole 20 mg enteric tablet, 30**

| 12287Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole GH [GQ] |

| 12287Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Esomeprazole GxP [AF] | [a] Esomeprazole RBX [RA] |
| | | | | | | [a] Esomeprazole Viatris [MQ] | [a] ESOMEPRAZOLE-WGR [WG] |
| | | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | | [a] Nexole [RF] | |
| | | | [B]13.44 | 36.28 | 24.38 | [a] Nexium [AP] | |

## ESOMEPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of *Helicobacter pylori.*

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15856***

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; **OR**
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; **OR**
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; **OR**
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; **OR**
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

### esomeprazole 20 mg enteric tablet, 30

| 14481E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 4 | 5 | 0.00 | *31.32 | 25.00 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole GH [GQ] |
| | | | | | | [a] Esomeprazole GxP [AF] | [a] Esomeprazole RBX [RA] |
| | | | | | | [a] Esomeprazole Viatris [MQ] | [a] ESOMEPRAZOLE-WGR [WG] |
| | | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | | [a] Nexole [RF] | |
| | | | [B]26.88 | 58.20 | 25.00 | [a] Nexium [AP] | |

**esomeprazole 20 mg enteric capsule, 30**

14537D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | 0.00 | *31.32 | 25.00 | [a] Noxicid Caps [AL] |

## ESOMEPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of *Helicobacter pylori.*

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A high dose proton pump inhibitor is: esomeprazole 40 mg.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** This authority approval must be sought by the specified specialist prescriber.

**Authority Required**

***11370***

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a high dose proton pump inhibitor (PPI) administered once daily, (ii) a standard dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; **OR**
- Patient must be assessed for the risks/benefits of a step-down in dosing from a high dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; **OR**
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; **OR**
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**esomeprazole 40 mg enteric tablet, 30**

12283L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *28.52 | 25.00 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole GH [GQ] |
| | | | | | [a] Esomeprazole GxP [AF] | [a] Esomeprazole RBX [RA] |
| | | | | | [a] Esomeprazole Viatris [MQ] | [a] ESOMEPRAZOLE-WGR [WG] |
| | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | [a] Nexole [RF] | |
| | | [B]13.58 | 42.10 | 25.00 | [a] Nexium [AP] | |

**esomeprazole 40 mg enteric capsule, 30**

12290W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *28.52 | 25.00 | [a] Noxicid Caps [AL] |

## ESOMEPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of *Helicobacter pylori.*

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A high dose proton pump inhibitor is: esomeprazole 40 mg.

**Note** Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** This authority approval must be sought by the specified specialist prescriber.

**Authority Required**

***15936***

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a high dose proton pump inhibitor (PPI) administered once daily, (ii) a standard dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; **OR**
- Patient must be assessed for the risks/benefits of a step-down in dosing from a high dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; **OR**
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; **OR**
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**esomeprazole 40 mg enteric capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14445G | 4 | 5 | 0.00 | *42.68 | 25.00 | [a] Noxicid Caps [AL] |

**esomeprazole 40 mg enteric tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14512T | 4 | 5 | 0.00 | *42.68 | 25.00 | [a] APO-Esomeprazole [TY] | [a] Esomeprazole GH [GQ] |
| | | | | | | [a] Esomeprazole GxP [AF] | [a] Esomeprazole RBX [RA] |
| | | | | | | [a] Esomeprazole Viatris [MQ] | [a] ESOMEPRAZOLE-WGR [WG] |
| | | | | | | [a] Esopreze [BG] | [a] Nexazole [RW] |
| | | | | | | [a] Nexole [RF] | |
| | | | [B]27.16 | 69.84 | 25.00 | [a] Nexium [AP] | |

## LANSOPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Restricted benefit**

***5444***

Gastro-oesophageal reflux disease

**Restricted benefit**

***5512***

Scleroderma oesophagus

**lansoprazole 15 mg enteric capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8198L NP | 1 | 5 | 0.00 | 18.10 | 19.64 | Zopral [AF] |

**lansoprazole 15 mg orally disintegrating tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9331D NP | 1 | 5 | 0.00 | 18.02 | 19.56 | [a] APO-Lansoprazole ODT [TX] | [a] Lansoprazole ODT GH [GQ] |
| | | | | | | [a] Zopral ODT [AF] | |
| | | | [B]4.57 | 22.59 | 19.56 | [a] Zoton FasTabs [PF] | |

## LANSOPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Restricted benefit**

***15574***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

***15633***

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**lansoprazole 15 mg orally disintegrating tablet, 28**

| 14374M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.68 | 23.22 | [a] APO-Lansoprazole ODT [TX] | [a] Lansoprazole ODT GH [GQ] |
| | | | | | | [a] Zopral ODT [AF] | |
| | | | [B]9.14 | 30.82 | 23.22 | [a] Zoton FasTabs [PF] | |

**lansoprazole 15 mg enteric capsule, 30**

| 14448K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | Zopral [AF] |

## LANSOPRAZOLE

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority Required (STREAMLINED)**

***8780***

Scleroderma oesophagus

**lansoprazole 30 mg enteric capsule, 28**

| 2241Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Lansoprazole [TX] | [a] Lanzopran [RA] |
| | | | | | | [a] Zopral [AF] | |

**lansoprazole 30 mg orally disintegrating tablet, 28**

| 9478W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Lansoprazole ODT [TX] | [a] Lansoprazole ODT GH [GQ] |
| | | | | | | [a] Zopral ODT [AF] | |
| | | | [B]4.47 | 23.07 | 20.14 | [a] Zoton FasTabs [PF] | |

## LANSOPRAZOLE

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority Required (STREAMLINED)**

***15658***

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**lansoprazole 30 mg enteric capsule, 28**

| 14340R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Lansoprazole [TX] | [a] Lanzopran [RA] |
| | | | | | | [a] Zopral [AF] | |

**lansoprazole 30 mg orally disintegrating tablet, 28**

| 14342W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Lansoprazole ODT [TX] | [a] Lansoprazole ODT GH [GQ] |
| | | | | | | [a] Zopral ODT [AF] | |
| | | | [B]8.94 | 31.78 | 24.38 | [a] Zoton FasTabs [PF] | |

## LANSOPRAZOLE

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***8776***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**lansoprazole 30 mg enteric capsule, 28**

| 11669E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Lansoprazole [TX] | [a] Lanzopran [RA] |
| | | | | | | [a] Zopral [AF] | |

**lansoprazole 30 mg orally disintegrating tablet, 28**

| 11697P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Lansoprazole ODT [TX] | [a] Lansoprazole ODT GH [GQ] |
| | | | | | | [a] Zopral ODT [AF] | |
| | | | [B]4.47 | 23.07 | 20.14 | [a] Zoton FasTabs [PF] | |

## LANSOPRAZOLE

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15530***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**lansoprazole 30 mg enteric capsule, 28**

| 14302R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Lansoprazole [TX] | [a] Lanzopran [RA] |
| | | | | | | [a] Zopral [AF] | |

**lansoprazole 30 mg orally disintegrating tablet, 28**

| 14406F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Lansoprazole ODT [TX] | [a] Lansoprazole ODT GH [GQ] |
| | | | | | | [a] Zopral ODT [AF] | |
| | | | [B]8.94 | 31.78 | 24.38 | [a] Zoton FasTabs [PF] | |

## LANSOPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of *Helicobacter pylori.*

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***11310***

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; **OR**
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; **OR**
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; **OR**
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; **OR**
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**lansoprazole 30 mg orally disintegrating tablet, 28**

| 12276D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Lansoprazole ODT [TX] | [a] Lansoprazole ODT GH [GQ] |
| | | | | | | [a] Zopral ODT [AF] | |
| | | | [B]8.94 | 31.78 | 24.38 | [a] Zoton FasTabs [PF] | |

**lansoprazole 30 mg enteric capsule, 28**

| 12284M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Lansoprazole [TX] | [a] Lanzopran [RA] |
| | | | | | | [a] Zopral [AF] | |

## LANSOPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of *Helicobacter pylori.*

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15856***

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; **OR**
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; **OR**
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; **OR**
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; **OR**
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

### lansoprazole 30 mg enteric capsule, 28

14304W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4 | 5 | 0.00 | *31.32 | 25.00 | [a] APO-Lansoprazole [TX] | [a] Lanzopran [RA] |
| | | | | | [a] Zopral [AF] | |

### lansoprazole 30 mg orally disintegrating tablet, 28

14339Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4 | 5 | 0.00 | *31.32 | 25.00 | [a] APO-Lansoprazole ODT [TX] | [a] Lansoprazole ODT GH [GQ] |
| | | | | | [a] Zopral ODT [AF] | |
| | | [B]17.88 | 49.20 | 25.00 | [a] Zoton FasTabs [PF] | |

## LANSOPRAZOLE

**Note** Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***8775***

Peptic ulcer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have tested negative for helicobacter pylori infection; **OR**
- Patient must have failed treatment with helicobacter pylori eradication therapy.

**Authority Required (STREAMLINED)**

***8774***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; **OR**

- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

**lansoprazole 30 mg enteric capsule, 28**

| 2240X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 18.60 | 20.14 | [a] APO-Lansoprazole [TX] | [a] Lanzopran [RA] |
| | | | | | | [a] Zopral [AF] | |

**lansoprazole 30 mg orally disintegrating tablet, 28**

| 9477T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 18.60 | 20.14 | [a] APO-Lansoprazole ODT [TX] | [a] Lansoprazole ODT GH [GQ] |
| | | | | | | [a] Zopral ODT [AF] | |
| | | | [B]4.47 | 23.07 | 20.14 | [a] Zoton FasTabs [PF] | |

## OMEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Restricted benefit**
***5444***
Gastro-oesophageal reflux disease

**omeprazole 10 mg enteric tablet, 30**

| 14702T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 5 | 0.00 | 18.10 | 19.64 | Losec Tablets [PB] |

## OMEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Restricted benefit**
***5512***
Scleroderma oesophagus
**Restricted benefit**
***5529***
Zollinger-Ellison syndrome

**omeprazole 10 mg enteric tablet, 30**

| 8332M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | Losec Tablets [PB] |

## OMEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Restricted benefit**
***15574***
Gastro-oesophageal reflux disease
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**
***15633***
Scleroderma oesophagus
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**
***15575***
Zollinger-Ellison syndrome
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**omeprazole 10 mg enteric tablet, 30**

| 14432N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | Losec Tablets [PB] |

## OMEPRAZOLE

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.
**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.
**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority Required (STREAMLINED)**
***8780***
Scleroderma oesophagus
**Authority Required (STREAMLINED)**
***8866***
Zollinger-Ellison syndrome

**omeprazole 20 mg enteric capsule, 30**

| 1327W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Omeprazole [TX] | [a] Maxor [AF] |
| | | | | | | [a] OMEPRAZOLE CAPS WGR [WG] | [a] Omeprazole Sandoz [HX] |
| | | | | | | [a] Pharmacor Omeprazole 20 [CR] | [a] Probitor [SZ] |

**omeprazole 20 mg enteric tablet, 30**

| 8333N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Omeprazole [TX] | [a] Maxor EC Tabs [AF] |
| | | | | | | [a] OMEPRAZOLE-WGR [WG] | [a] Ozmep [RW] |

**omeprazole 20 mg enteric tablet, 30**

| 9110L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] Acimax Tablets [FJ] | [a] Omepral [FQ] |
| | | | | | | [a] Omeprazole Sandoz [SZ] | |
| | | | [B]6.87 | 25.47 | 20.14 | [a] Losec Tablets [PB] | |

## OMEPRAZOLE

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.
**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.
**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.
**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority Required (STREAMLINED)**
***15658***
Scleroderma oesophagus
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required (STREAMLINED)**
***15678***
Zollinger-Ellison syndrome
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**omeprazole 20 mg enteric tablet, 30**

| 14364B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Omeprazole [TX] | [a] Maxor EC Tabs [AF] |
| | | | | | | [a] OMEPRAZOLE-WGR [WG] | [a] Ozmep [RW] |

**omeprazole 20 mg enteric tablet, 30**

| 14397R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] Acimax Tablets [FJ] | [a] Omepral [FQ] |
| | | | | | | [a] Omeprazole Sandoz [SZ] | |
| | | | [B]13.74 | 36.58 | 24.38 | [a] Losec Tablets [PB] | |

**omeprazole 20 mg enteric capsule, 30**

| 14559G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Omeprazole [TX] | [a] Maxor [AF] |
| | | | | | | [a] OMEPRAZOLE CAPS WGR [WG] | [a] Omeprazole Sandoz [HX] |
| | | | | | | [a] Pharmacor Omeprazole 20 [CR] | [a] Probitor [SZ] |

## OMEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.
**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.
**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.
**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***8775***
Peptic ulcer
Treatment Phase: Initial treatment
**Clinical criteria:**

- Patient must have tested negative for helicobacter pylori infection; **OR**
- Patient must have failed treatment with helicobacter pylori eradication therapy.

**omeprazole 20 mg enteric capsule, 30**

| 1326T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 18.60 | 20.14 | [a] APO-Omeprazole [TX] | [a] Maxor [AF] |
| | | | | | | [a] OMEPRAZOLE CAPS WGR [WG] | [a] Omeprazole Sandoz [HX] |
| | | | | | | [a] Pharmacor Omeprazole 20 [CR] | [a] Probitor [SZ] |

**omeprazole 20 mg enteric tablet, 30**

| 8331L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 18.60 | 20.14 | [a] APO-Omeprazole [TX] | [a] Maxor EC Tabs [AF] |
| | | | | | | [a] OMEPRAZOLE-WGR [WG] | [a] Ozmep [RW] |

**omeprazole 20 mg enteric tablet, 30**

| 9109K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 18.60 | 20.14 | [a] Acimax Tablets [FJ] | [a] Omepral [FQ] |
| | | | | | | [a] Omeprazole Sandoz [SZ] | |
| | | | [B]6.87 | 25.47 | 20.14 | [a] Losec Tablets [PB] | |

## OMEPRAZOLE

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.
**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.
**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.
**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***8776***
Gastro-oesophageal reflux disease
**Clinical criteria:**

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**omeprazole 20 mg enteric tablet, 30**

| 11677N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] Acimax Tablets [FJ] | [a] Omepral [FQ] |
| | | | | | | [a] Omeprazole Sandoz [SZ] | |
| | | | [B]6.87 | 25.47 | 20.14 | [a] Losec Tablets [PB] | |

**omeprazole 20 mg enteric tablet, 30**

| 11683X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Omeprazole [TX] | [a] Maxor EC Tabs [AF] |
| | | | | | | [a] OMEPRAZOLE-WGR [WG] | [a] Ozmep [RW] |

**omeprazole 20 mg enteric capsule, 30**

| 11682W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Omeprazole [TX] | [a] Maxor [AF] |

| 11682W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] OMEPRAZOLE CAPS WGR [WG] | [a] Omeprazole Sandoz [HX] |
| | | | | | | [a] Pharmacor Omeprazole 20 [CR] | [a] Probitor [SZ] |

## OMEPRAZOLE

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15530***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

### omeprazole 20 mg enteric capsule, 30

| 14464G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Omeprazole [TX] | [a] Maxor [AF] |
| | | | | | | [a] OMEPRAZOLE CAPS WGR [WG] | [a] Omeprazole Sandoz [HX] |
| | | | | | | [a] Pharmacor Omeprazole 20 [CR] | [a] Probitor [SZ] |

### omeprazole 20 mg enteric tablet, 30

| 14533X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Omeprazole [TX] | [a] Maxor EC Tabs [AF] |
| | | | | | | [a] OMEPRAZOLE-WGR [WG] | [a] Ozmep [RW] |

### omeprazole 20 mg enteric tablet, 30

| 14557E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] Acimax Tablets [FJ] | [a] Omepral [FQ] |
| | | | | | | [a] Omeprazole Sandoz [SZ] | |
| | | | [B]13.74 | 36.58 | 24.38 | [a] Losec Tablets [PB] | |

## OMEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***8774***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; **OR**
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

### omeprazole 20 mg enteric capsule, 30

| 14706B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 18.60 | 20.14 | [a] APO-Omeprazole [TX] | [a] Maxor [AF] |
| | | | | | | [a] OMEPRAZOLE CAPS WGR [WG] | [a] Omeprazole Sandoz [HX] |
| | | | | | | [a] Pharmacor Omeprazole 20 [CR] | [a] Probitor [SZ] |

**omeprazole 20 mg enteric tablet, 30**

| 14707C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 18.60 | 20.14 | [a] Acimax Tablets [FJ] | [a] Omepral [FQ] |
| | | | | | | [a] Omeprazole Sandoz [SZ] | |
| | | | [B]6.87 | 25.47 | 20.14 | [a] Losec Tablets [PB] | |

**omeprazole 20 mg enteric tablet, 30**

| 14708D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 18.60 | 20.14 | [a] APO-Omeprazole [TX] | [a] Maxor EC Tabs [AF] |
| | | | | | | [a] OMEPRAZOLE-WGR [WG] | [a] Ozmep [RW] |

## OMEPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of *Helicobacter pylori.*

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***11310***

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; **OR**
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; **OR**
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; **OR**
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; **OR**
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**omeprazole 20 mg enteric tablet, 30**

| 12270T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] Acimax Tablets [FJ] | [a] Omepral [FQ] |
| | | | | | | [a] Omeprazole Sandoz [SZ] | |
| | | | [B]13.74 | 36.58 | 24.38 | [a] Losec Tablets [PB] | |

**omeprazole 20 mg enteric tablet, 30**

| 12272X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Omeprazole [TX] | [a] Maxor EC Tabs [AF] |
| | | | | | | [a] OMEPRAZOLE-WGR [WG] | [a] Ozmep [RW] |

**omeprazole 20 mg enteric capsule, 30**

12281J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Omeprazole [TX] | [a] Maxor [AF] |
| | | | | | [a] OMEPRAZOLE CAPS WGR [WG] | [a] Omeprazole Sandoz [HX] |
| | | | | | [a] Pharmacor Omeprazole 20 [CR] | [a] Probitor [SZ] |

## OMEPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of *Helicobacter pylori.*

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15856***

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; **OR**
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; **OR**
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; **OR**
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; **OR**
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**omeprazole 20 mg enteric tablet, 30**

14363Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4 | 5 | 0.00 | *31.32 | 25.00 | [a] Acimax Tablets [FJ] | [a] Omepral [FQ] |
| | | | | | [a] Omeprazole Sandoz [SZ] | |
| | | [B]27.48 | 58.80 | 25.00 | [a] Losec Tablets [PB] | |

**omeprazole 20 mg enteric tablet, 30**

14558F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4 | 5 | 0.00 | *31.32 | 25.00 | [a] APO-Omeprazole [TX] | [a] Maxor EC Tabs [AF] |
| | | | | | [a] OMEPRAZOLE-WGR [WG] | [a] Ozmep [RW] |

**omeprazole 20 mg enteric capsule, 30**

| 14465H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 4 | 5 | 0.00 | *31.32 | 25.00 | [a] APO-Omeprazole [TX] | [a] Maxor [AF] |
| | | | | | | [a] OMEPRAZOLE CAPS WGR [WG] | [a] Omeprazole Sandoz [HX] |
| | | | | | | [a] Pharmacor Omeprazole 20 [CR] | [a] Probitor [SZ] |

## PANTOPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Restricted benefit**

***5444***

Gastro-oesophageal reflux disease

**Restricted benefit**

***5512***

Scleroderma oesophagus

**Restricted benefit**

***5529***

Zollinger-Ellison syndrome

**pantoprazole 20 mg enteric tablet, 30**

| 8399C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Pantoprazole [TX] | [a] APX-PANTOPRAZOLE [TW] |
| | | | | | | [a] BTC Pantoprazole [BG] | [a] Ozpan [RA] |
| | | | | | | [a] Panthron [ZS] | [a] Pantoprazole generichealth [HQ] |
| | | | | | | [a] Pantoprazole Sandoz [SZ] | [a] PANTOPRAZOLE-WGR [WG] |
| | | | | | | [a] Salpraz [AF] | [a] Sozol [RW] |
| | | | [B]4.69 | 21.79 | 18.64 | [a] Somac [NQ] | |

## PANTOPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Restricted benefit**

***15574***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

***15633***

Scleroderma oesophagus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

***15575***

Zollinger-Ellison syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pantoprazole 20 mg enteric tablet, 30**

| 14501F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APO-Pantoprazole [TX] | [a] APX-PANTOPRAZOLE [TW] |
| | | | | | | [a] BTC Pantoprazole [BG] | [a] Ozpan [RA] |
| | | | | | | [a] Panthron [ZS] | [a] Pantoprazole generichealth [HQ] |
| | | | | | | [a] Pantoprazole Sandoz [SZ] | [a] PANTOPRAZOLE-WGR [WG] |
| | | | | | | [a] Salpraz [AF] | [a] Sozol [RW] |
| | | | [B]9.38 | 29.22 | 21.38 | [a] Somac [NQ] | |

## PANTOPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.
**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority Required (STREAMLINED)**
***8780***
Scleroderma oesophagus
**Authority Required (STREAMLINED)**
***8866***
Zollinger-Ellison syndrome

**pantoprazole 40 mg enteric tablet, 30**

| 8008L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.47 | 19.01 | [a] APO-Pantoprazole [TX] | [a] APX-PANTOPRAZOLE [TW] |
| | | | | | | [a] BTC Pantoprazole [BG] | [a] I-Pantoprazole [CR] |
| | | | | | | [a] Ozpan [RA] | [a] Panthron [ZS] |
| | | | | | | [a] Pantoprazole generichealth [HQ] | [a] Pantoprazole Sandoz [SZ] |
| | | | | | | [a] PANTOPRAZOLE-WGR [WG] | [a] Salpraz [AF] |
| | | | | | | [a] Sozol [RW] | |
| | | | [B]4.69 | 22.16 | 19.01 | [a] Somac [NQ] | |

**pantoprazole 40 mg enteric coated granules, 30 sachets**

| 9424B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 34.84 | 25.00 | Somac [NQ] |

## PANTOPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.
**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.
**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority Required (STREAMLINED)**
***15658***
Scleroderma oesophagus
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required (STREAMLINED)**
***15678***
Zollinger-Ellison syndrome
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pantoprazole 40 mg enteric tablet, 30**

| 14330F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *20.58 | 22.12 | [a] APO-Pantoprazole [TX] | [a] APX-PANTOPRAZOLE [TW] |
| | | | | | | [a] BTC Pantoprazole [BG] | [a] I-Pantoprazole [CR] |
| | | | | | | [a] Ozpan [RA] | [a] Panthron [ZS] |
| | | | | | | [a] Pantoprazole generichealth [HQ] | [a] Pantoprazole Sandoz [SZ] |
| | | | | | | [a] PANTOPRAZOLE-WGR [WG] | [a] Salpraz [AF] |
| | | | | | | [a] Sozol [RW] | |
| | | | [B]9.38 | 29.96 | 22.12 | [a] Somac [NQ] | |

**pantoprazole 40 mg enteric coated granules, 30 sachets**

| 14466J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *55.32 | 25.00 | Somac [NQ] |

## PANTOPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.
**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.
**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.
**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***8776***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**pantoprazole 40 mg enteric coated granules, 30 sachets**

| 11678P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 34.84 | 25.00 | Somac [NQ] |

**pantoprazole 40 mg enteric tablet, 30**

| 11681T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.47 | 19.01 | [a] APO-Pantoprazole [TX] | [a] APX-PANTOPRAZOLE [TW] |
| | | | | | | [a] BTC Pantoprazole [BG] | [a] I-Pantoprazole [CR] |
| | | | | | | [a] Ozpan [RA] | [a] Panthron [ZS] |
| | | | | | | [a] Pantoprazole generichealth [HQ] | [a] Pantoprazole Sandoz [SZ] |
| | | | | | | [a] PANTOPRAZOLE-WGR [WG] | [a] Salpraz [AF] |
| | | | | | | [a] Sozol [RW] | |
| | | | [B]4.69 | 22.16 | 19.01 | [a] Somac [NQ] | |

## PANTOPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15530***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**pantoprazole 40 mg enteric tablet, 30**

| 14362X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *20.58 | 22.12 | [a] APO-Pantoprazole [TX] | [a] APX-PANTOPRAZOLE [TW] |
| | | | | | | [a] BTC Pantoprazole [BG] | [a] I-Pantoprazole [CR] |
| | | | | | | [a] Ozpan [RA] | [a] Panthron [ZS] |
| | | | | | | [a] Pantoprazole generichealth [HQ] | [a] Pantoprazole Sandoz [SZ] |
| | | | | | | [a] PANTOPRAZOLE-WGR [WG] | [a] Salpraz [AF] |
| | | | | | | [a] Sozol [RW] | |
| | | | [B]9.38 | 29.96 | 22.12 | [a] Somac [NQ] | |

**pantoprazole 40 mg enteric coated granules, 30 sachets**

| 14500E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *55.32 | 25.00 | Somac [NQ] |

## PANTOPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of *Helicobacter pylori.*

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***11310***

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; **OR**
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; **OR**
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; **OR**
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; **OR**
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**pantoprazole 40 mg enteric tablet, 30**

12277E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *20.58 | 22.12 | [a] APO-Pantoprazole [TX] | [a] APX-PANTOPRAZOLE [TW] |
| | | | | | [a] BTC Pantoprazole [BG] | [a] I-Pantoprazole [CR] |
| | | | | | [a] Ozpan [RA] | [a] Panthron [ZS] |
| | | | | | [a] Pantoprazole generichealth [HQ] | [a] Pantoprazole Sandoz [SZ] |
| | | | | | [a] PANTOPRAZOLE-WGR [WG] | [a] Salpraz [AF] |
| | | | | | [a] Sozol [RW] | |
| | | [B]9.38 | 29.96 | 22.12 | [a] Somac [NQ] | |

**pantoprazole 40 mg enteric coated granules, 30 sachets**

12282K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *55.32 | 25.00 | Somac [NQ] |

## PANTOPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of *Helicobacter pylori.*
**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.
**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15856***

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; **OR**
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; **OR**
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; **OR**
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; **OR**
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

### pantoprazole 40 mg enteric tablet, 30

| 14394N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 4 | 5 | 0.00 | *26.80 | 25.00 | [a] APO-Pantoprazole [TX] | [a] APX-PANTOPRAZOLE [TW] |
| | | | | | | [a] BTC Pantoprazole [BG] | [a] I-Pantoprazole [CR] |
| | | | | | | [a] Ozpan [RA] | [a] Panthron [ZS] |
| | | | | | | [a] Pantoprazole generichealth [HQ] | [a] Pantoprazole Sandoz [SZ] |
| | | | | | | [a] PANTOPRAZOLE-WGR [WG] | [a] Salpraz [AF] |
| | | | | | | [a] Sozol [RW] | |
| | | | [B]18.76 | 45.56 | 25.00 | [a] Somac [NQ] | |

### pantoprazole 40 mg enteric coated granules, 30 sachets

| 14395P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 5 | 0.00 | *96.28 | 25.00 | Somac [NQ] |

## PANTOPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***8775***

Peptic ulcer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have tested negative for helicobacter pylori infection; **OR**
- Patient must have failed treatment with helicobacter pylori eradication therapy.

**Authority Required (STREAMLINED)**

***8774***

Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; **OR**
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

**pantoprazole 40 mg enteric tablet, 30**

| 8007K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 17.47 | 19.01 | [a] APO-Pantoprazole [TX] | [a] APX-PANTOPRAZOLE [TW] |
| | | | | | | [a] BTC Pantoprazole [BG] | [a] I-Pantoprazole [CR] |
| | | | | | | [a] Ozpan [RA] | [a] Panthron [ZS] |
| | | | | | | [a] Pantoprazole generichealth [HQ] | [a] Pantoprazole Sandoz [SZ] |
| | | | | | | [a] PANTOPRAZOLE-WGR [WG] | [a] Salpraz [AF] |
| | | | | | | [a] Sozol [RW] | |
| | | | [B]4.69 | 22.16 | 19.01 | [a] Somac [NQ] | |

**pantoprazole 40 mg enteric coated granules, 30 sachets**

| 9423Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 34.84 | 25.00 | Somac [NQ] |

## RABEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Restricted benefit**
***5444***
Gastro-oesophageal reflux disease
**Restricted benefit**
***5512***
Scleroderma oesophagus

**rabeprazole sodium 10 mg enteric tablet, 28**

| 8507R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.93 | 19.47 | [a] APO-Rabeprazole [TX] | [a] Parbezol [RW] |
| | | | | | | [a] Rabeprazole Sandoz [SZ] | [a] Rabeprazole Viatris [AF] |
| | | | | | | [a] RABEPRAZOLE-WGR [WG] | |

## RABEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Restricted benefit**
***15574***
Gastro-oesophageal reflux disease
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**
***15633***
Scleroderma oesophagus
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**rabeprazole sodium 10 mg enteric tablet, 28**

| 14502G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.50 | 23.04 | [a] APO-Rabeprazole [TX] | [a] Parbezol [RW] |
| | | | | | | [a] Rabeprazole Sandoz [SZ] | [a] Rabeprazole Viatris [AF] |
| | | | | | | [a] RABEPRAZOLE-WGR [WG] | |

## RABEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.
**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.
**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority Required (STREAMLINED)**
***8780***
Scleroderma oesophagus

**rabeprazole sodium 20 mg enteric tablet, 30**

| 8508T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.93 | 19.47 | [a] APO-Rabeprazole [TX] | [a] Parbezol [RW] |
| | | | | | | [a] Rabeprazole Mylan [AF] | [a] Rabeprazole Sandoz [SZ] |

| 8508T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Rabeprazole SUN [RN] | [a] RABEPRAZOLE-WGR [WG] |
| | | | | | | [a] Zabep [AL] | |

## RABEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.
**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.
**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority Required (STREAMLINED)**
***15658***
Scleroderma oesophagus
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**rabeprazole sodium 20 mg enteric tablet, 30**

| 14433P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.50 | 23.04 | [a] APO-Rabeprazole [TX] | [a] Parbezol [RW] |
| | | | | | | [a] Rabeprazole Mylan [AF] | [a] Rabeprazole Sandoz [SZ] |
| | | | | | | [a] Rabeprazole SUN [RN] | [a] RABEPRAZOLE-WGR [WG] |
| | | | | | | [a] Zabep [AL] | |

## RABEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.
**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.
**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***8776***
Gastro-oesophageal reflux disease
**Clinical criteria:**

- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**rabeprazole sodium 20 mg enteric tablet, 30**

| 11670F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.93 | 19.47 | [a] APO-Rabeprazole [TX] | [a] Parbezol [RW] |
| | | | | | | [a] Rabeprazole Mylan [AF] | [a] Rabeprazole Sandoz [SZ] |
| | | | | | | [a] Rabeprazole SUN [RN] | [a] RABEPRAZOLE-WGR [WG] |
| | | | | | | [a] Zabep [AL] | |

## RABEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.
**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.
**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***15530***
Gastro-oesophageal reflux disease
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

**rabeprazole sodium 20 mg enteric tablet, 30**

| 14463F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.50 | 23.04 | [a] APO-Rabeprazole [TX] | [a] Parbezol [RW] |
| | | | | | | [a] Rabeprazole Mylan [AF] | [a] Rabeprazole Sandoz [SZ] |
| | | | | | | [a] Rabeprazole SUN [RN] | [a] RABEPRAZOLE-WGR [WG] |

| 14463F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Zabep [AL] | |

## RABEPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of *Helicobacter pylori.*

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***11310***

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; **OR**
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; **OR**
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; **OR**
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; **OR**
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

### rabeprazole sodium 20 mg enteric tablet, 30

| 12286P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *21.50 | 23.04 | [a] APO-Rabeprazole [TX] | [a] Parbezol [RW] |
| | | | | | | [a] Rabeprazole Mylan [AF] | [a] Rabeprazole Sandoz [SZ] |
| | | | | | | [a] Rabeprazole SUN [RN] | [a] RABEPRAZOLE-WGR [WG] |
| | | | | | | [a] Zabep [AL] | |

## RABEPRAZOLE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of *Helicobacter pylori.*

**Note** A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15856***

Complex gastro-oesophageal reflux disease (GORD)
Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; **OR**
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

**Clinical criteria:**

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; **OR**
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; **OR**
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; **OR**
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 2 packs per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

**rabeprazole sodium 20 mg enteric tablet, 30**

14396Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 4 | 5 | 0.00 | *28.64 | 25.00 | [a] APO-Rabeprazole [TX] | [a] Parbezol [RW] |
| | | | | | [a] Rabeprazole Mylan [AF] | [a] Rabeprazole Sandoz [SZ] |
| | | | | | [a] Rabeprazole SUN [RN] | [a] RABEPRAZOLE-WGR [WG] |
| | | | | | [a] Zabep [AL] | |

## RABEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.
**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.
**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***8775***
Peptic ulcer
Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have tested negative for helicobacter pylori infection; **OR**
- Patient must have failed treatment with helicobacter pylori eradication therapy.

**Authority Required (STREAMLINED)**
***8774***
Gastro-oesophageal reflux disease

**Clinical criteria:**

- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; **OR**
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

**rabeprazole sodium 20 mg enteric tablet, 30**

8509W
NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 17.93 | 19.47 | [a] APO-Rabeprazole [TX] | [a] Parbezol [RW] |
| | | | | | [a] Rabeprazole Mylan [AF] | [a] Rabeprazole Sandoz [SZ] |
| | | | | | [a] Rabeprazole SUN [RN] | [a] RABEPRAZOLE-WGR [WG] |

| 8509W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Zabep [AL] | |

### *Combinations for eradication of Helicobacter pylori*

## ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXICILLIN

**Restricted benefit**

***6118***

Eradication of Helicobacter pylori

**Clinical criteria:**

- The condition must be associated with peptic ulcer disease.

**Note** Pharmaceutical benefits that have the form pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium trihydrate), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate) and pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate) are equivalent for the purposes of substitution.

**esomeprazole 20 mg enteric tablet [14] (&) amoxicillin 500 mg capsule [28] (&) clarithromycin 500 mg tablet [14], 1 pack**

| 8738X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 4.82 | 40.76 | 25.00 | [a] Nexium Hp7 [AP] |

**esomeprazole 20 mg enteric tablet [14] (&) amoxicillin 500 mg capsule [28] (&) clarithromycin 500 mg tablet [14], 1 pack**

| 10759G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 35.94 | 25.00 | [a] ESOMEPRAZOLE SANDOZ Hp7 [SZ] |

# DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

## BELLADONNA AND DERIVATIVES, PLAIN

### *Belladonna alkaloids, tertiary amines*

## ATROPINE SULFATE

**atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules**

| 1089H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 29.87 | 25.00 | Atropine Injection (Bridgewest) [WZ] |

**atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules**

| 5022H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 29.87 | 25.00 | Atropine Injection (Bridgewest) [WZ] |

## PROPULSIVES

### *Propulsives*

## DOMPERIDONE

**domperidone 10 mg tablet, 25**

| 1347X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 16.45 | 17.99 | [a] APO-DOMPERIDONE [TX] | [a] Motilium [JT] |

## METOCLOPRAMIDE

**metoclopramide hydrochloride 10 mg tablet, 25**

| 1207M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Metoclopramide [TX] | [a] EMEXLON [RW] |
| | | | | | | [a] METOCLOPRAMIDE-WGR [WG] | [a] Pramin [AF] |
| | | | [B]3.31 | 20.41 | 18.64 | [a] Maxolon [IL] | |

**metoclopramide hydrochloride 10 mg tablet, 25**

| 5151D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Metoclopramide [TX] | [a] EMEXLON [RW] |
| | | | | | | [a] METOCLOPRAMIDE-WGR [WG] | [a] Pramin [AF] |
| | | | [B]3.31 | 20.41 | 18.64 | [a] Maxolon [IL] | |

**metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules**

| 1206L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 21.77 | 23.31 | [a] Metoclopramide HCl Medsurge [DZ] | [a] METOCLOPRAMIDE INJECTION BP [WZ] |

**metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules**

| 5153F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 21.77 | 23.31 | [a] Metoclopramide HCl Medsurge [DZ] | [a] METOCLOPRAMIDE INJECTION BP [WZ] |

# ANTIEMETICS AND ANTINAUSEANTS

## ANTIEMETICS AND ANTINAUSEANTS

### *Serotonin (5HT3) antagonists*

### FOSNETUPITANT + PALONOSETRON

**Note** This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

**Note** Various sources of information outline the emetic risk associated with cancer treatment. Examples include the National Comprehensive Cancer Network guidelines (USA), eviQ guidelines and approved Product Information of individual drugs. These examples are not a comprehensive list of which anti-cancer drugs that have moderate to high emesis risk.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***14387***

Nausea and vomiting

**Clinical criteria:**

- The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy, **AND**
- The treatment must be in combination with dexamethasone, unless contraindicated, **AND**
- Patient must be unable to swallow; **OR**
- Patient must be contraindicated to oral anti-emetics.

**fosnetupitant 235 mg + palonosetron 250 microgram injection, 1 vial**

| 13640X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 109.55 | 25.00 | Akynzeo IV [XT] |

### GRANISETRON

**Restricted benefit**

***4118***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

**granisetron 2 mg tablet, 1**

| 8728J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *31.66 | 25.00 | Kytril [IX] |

### GRANISETRON

**Authority Required (STREAMLINED)**

***10498***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy; **OR**
- The condition must be associated with oral chemotherapy being used to treat malignancy.

**granisetron 2 mg tablet, 5**

| 8873B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 57.59 | 25.00 | Kytril [IX] |

### NETUPITANT + PALONOSETRON

**Note** This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

**Note** Various sources of information outline the emetic risk associated with cancer treatment. Examples include the National Comprehensive Cancer Network guidelines (USA), eviQ guidelines and approved Product Information of individual drugs. These examples are not a comprehensive list of which anti-cancer drugs that have moderate to high emesis risk.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***14443***

Nausea and vomiting

**Clinical criteria:**

- The treatment must be in combination with dexamethasone, unless contraindicated, **AND**
- The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy.

**netupitant 300 mg + palonosetron 500 microgram capsule, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10731T NP | ‡1 | 5 | 0.00 | 99.53 | 25.00 | Akynzeo [XT] |

## ONDANSETRON

**Authority Required (STREAMLINED)**

***15193***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy; **OR**
- The condition must be associated with chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions.

**ondansetron 4 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1594X NP | 1 | 1 | 0.00 | 23.49 | 25.00 | [a] APX-Ondansetron [TY] | [a] Ondansetron-DRLA [RZ] |
| | | | | | | [a] Ondansetron SZ [HX] | [a] Ondansetron Tablets Viatris [AL] |
| | | | | | | [a] Ondansetron VTRS [AF] | [a] ONDANSETRON-WGR [WG] |
| | | | | | | [a] Zofran [AS] | [a] Zotren 4 [RF] |

**ondansetron 4 mg/5 mL oral liquid, 50 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8233H NP | ‡1 | 1 | 0.00 | 98.61 | 25.00 | [a] ONDANSETRON-AFT [AE] | [a] Zofran syrup 50 mL [AS] |

**ondansetron 8 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1595Y NP | 1 | 1 | 0.00 | 25.66 | 25.00 | [a] APX-Ondansetron [TY] | [a] Ondansetron-DRLA [RZ] |
| | | | | | | [a] Ondansetron SZ [HX] | [a] Ondansetron Tablets Viatris [AL] |
| | | | | | | [a] Ondansetron VTRS [AF] | [a] ONDANSETRON-WGR [WG] |
| | | | | | | [a] Zofran [AS] | [a] Zotren 8 [RF] |

## ONDANSETRON

**Restricted benefit**

***5618***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

**ondansetron 4 mg orally disintegrating tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5470X NP | 1 | 0 | 0.00 | 18.10 | 19.64 | [a] APX-Ondansetron ODT [TY] | [a] Ondansetron ODT-DRLA [RZ] |
| | | | | | | [a] Ondansetron ODT Viatris [AL] | [a] ONDANSETRON ODT-WGR [WG] |
| | | | | | | [a] Ondansetron SZ ODT [HX] | [a] Zotren ODT [RF] |

**ondansetron 8 mg orally disintegrating tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5471Y NP | 1 | 0 | 0.00 | 18.93 | 20.47 | [a] APX-Ondansetron ODT [TY] | [a] Ondansetron ODT-DRLA [RZ] |
| | | | | | | [a] Ondansetron ODT Viatris [AL] | [a] Ondansetron ODT VTRS [MQ] |
| | | | | | | [a] ONDANSETRON ODT-WGR [WG] | [a] Ondansetron SZ ODT [HX] |
| | | | | | | [a] Zotren ODT [RF] | |

## ONDANSETRON

**Restricted benefit**

***4118***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

### ondansetron 4 mg tablet, 4

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8224W NP | 1 | 0 | 0.00 | 18.10 | 19.64 | [a] APX-Ondansetron [TY] | [a] Ondansetron-DRLA [RZ] |
| | | | | | | [a] Ondansetron SZ [HX] | [a] Ondansetron Tablets Viatris [AL] |
| | | | | | | [a] Ondansetron VTRS [AF] | [a] ONDANSETRON-WGR [WG] |
| | | | | | | [a] Zofran [AS] | [a] Zotren 4 [RF] |

### ondansetron 8 mg tablet, 4

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8225X NP | 1 | 0 | 0.00 | 18.93 | 20.47 | [a] APX-Ondansetron [TY] | [a] Ondansetron-DRLA [RZ] |
| | | | | | | [a] Ondansetron SZ [HX] | [a] Ondansetron Tablets Viatris [AL] |
| | | | | | | [a] Ondansetron VTRS [AF] | [a] ONDANSETRON-WGR [WG] |
| | | | | | | [a] Zofran [AS] | [a] Zotren 8 [RF] |

## ONDANSETRON

**Restricted benefit**

***5721***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

### ondansetron 4 mg/5 mL oral liquid, 50 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9441X NP | ‡1 | 0 | 0.00 | 98.61 | 25.00 | [a] ONDANSETRON-AFT [AE] | [a] Zofran syrup 50 mL [AS] |

## ONDANSETRON

**Note** Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 4 mg and pharmaceutical benefits that have the form ondansetron 4 mg wafer are equivalent for the purposes of substitution.

**Authority Required (STREAMLINED)**

***15193***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy; **OR**
- The condition must be associated with chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions.

### ondansetron 4 mg orally disintegrating tablet, 10

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5472B NP | 1 | 1 | 0.00 | 23.49 | 25.00 | [a] APX-Ondansetron ODT [TY] | [a] Ondansetron ODT-DRLA [RZ] |
| | | | | | | [a] Ondansetron ODT Lupin [HQ] | [a] Ondansetron ODT Viatris [AL] |
| | | | | | | [a] Ondansetron ODT VTRS [MQ] | [a] ONDANSETRON ODT-WGR [WG] |
| | | | | | | [a] Ondansetron SZ ODT [HX] | [a] Zotren ODT [RF] |

### ondansetron 4 mg wafer, 10

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8412R NP | 1 | 1 | 3.35 | 26.84 | 25.00 | [a] Zofran Zydis [AS] |

## ONDANSETRON

**Note** Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 8 mg and pharmaceutical benefits that have the form ondansetron 8 mg wafer are equivalent for the purposes of substitution.

**Authority Required (STREAMLINED)**

***15193***
Nausea and vomiting
**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy; **OR**
- The condition must be associated with chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions.

**ondansetron 8 mg orally disintegrating tablet, 10**

| 5473C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 25.66 | 25.00 | [a] APX-Ondansetron ODT [TY] | [a] Ondansetron ODT-DRLA [RZ] |
| | | | | | | [a] Ondansetron ODT Lupin [HQ] | [a] Ondansetron ODT Viatris [AL] |
| | | | | | | [a] Ondansetron ODT VTRS [MQ] | [a] ONDANSETRON ODT-WGR [WG] |
| | | | | | | [a] Ondansetron SZ ODT [HX] | [a] Zotren ODT [RF] |

**ondansetron 8 mg wafer, 10**

| 8413T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 3.34 | 31.66 | 25.00 | [a] Zofran Zydis [AS] |

## PALONOSETRON

**Restricted benefit**
***5686***
Nausea and vomiting
**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** This drug is not PBS-subsidised for administration with oral 5-HT3 antagonists.

**palonosetron 250 microgram/5 mL injection, 5 mL vial**

| 5295Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 24.70 | 25.00 | [a] Palonosetron Dr.Reddy's [RZ] | [a] Palonosetron JN [XT] |
| | | | | | | [a] PALONOSETRON Medsurge [DZ] | |

### *Other antiemetics*

## APREPITANT

**Authority Required (STREAMLINED)**
***4211***
Nausea and vomiting
**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.
**Note** Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***4215***
Nausea and vomiting
**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.
**Note** Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***6444***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must have had a prior episode of chemotherapy induced nausea or vomiting, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.

**Note** Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***6370***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.

**Note** Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

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**aprepitant 165 mg capsule, 1**

| 2518M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 66.01 | 25.00 | [a] Aprepitant APOTEX [TX] | [a] APREPITANT SCP [XC] |

## FOSAPREPITANT

**Authority Required (STREAMLINED)**

***6886***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

**Note** This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***6891***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

**Note** This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***6887***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must have had a prior episode of chemotherapy induced nausea or vomiting, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

**Note** This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***6852***

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

**Note** This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**fosaprepitant 150 mg injection, 1 vial**

| 11107N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 64.04 | 25.00 | [a] FOSAPREPITANT-AFT [AE] | [a] FOSAPREPITANT MEDSURGE [DZ] |
| | | | | | | [a] FOSAPREPITANT MSN [RQ] | |

## PROCHLORPERAZINE

**Caution** Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

**prochlorperazine maleate 5 mg tablet, 25**

| 5205Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Prochlorperazine [TX] | [a] ProCalm [RW] |
| | | | | | | [a] Prochlorperazine GH [GQ] | [a] Prochlorperazine Viatris [AF] |
| | | | | | | [a] PROCHLORPERAZINE-WGR [WG] | |
| | | | [B]2.79 | 19.89 | 18.64 | [a] Stemetil [IX] | |

**prochlorperazine mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules**

| 5206B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 30.69 | 25.00 | Stemetil [IX] |

## PROCHLORPERAZINE

**Caution** Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

**Note** As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.

**prochlorperazine maleate 5 mg tablet, 25**

| 2893G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Prochlorperazine [TX] | [a] ProCalm [RW] |
| | | | | | | [a] Prochlorperazine GH [GQ] | [a] Prochlorperazine Viatris [AF] |
| | | | | | | [a] PROCHLORPERAZINE-WGR [WG] | |
| | | | [B]2.79 | 19.89 | 18.64 | [a] Stemetil [IX] | |

**prochlorperazine mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules**

| 2369Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 30.69 | 25.00 | Stemetil [IX] |

# BILE AND LIVER THERAPY

## BILE THERAPY

### *Bile acids and derivatives*

## OBETICHOLIC ACID

**Caution** Hepatic decompensation and failure, in some cases fatal, have been reported in post-marketing reports in patients with moderate to severe hepatic impairment when dosed incorrectly.

**Note** Not for use in the treatment of sclerosing cholangitis.

**Note** Laboratory readings requested in this authority application must be no older than 52 weeks.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17548***

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; **OR**
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this drug, with treatment having commenced through one of: (i) the 'Initial treatment' listing, (ii) 'Grandfather' arrangements, **AND**
- Patient must be undergoing concurrent treatment with ursodeoxycholic acid; **OR**
- Patient must be undergoing treatment with this drug as monotherapy because treatment with ursodeoxycholic acid is not tolerated/contraindicated, **AND**
- Patient must not be undergoing concurrent treatment with elafibranor.

**Clinical criteria:**

- Patient must have achieved an adequate response to this drug, defined as having at least one of: (i) an alkaline phosphate (ALP) level less than 1.67 times the upper limit of normal (ULN), (ii) a reduction in the ALP reading of at least 15% compared to the baseline level provided with the initial authority application, (iii) a total bilirubin level within the normal reference range.

The improvement in the qualifying laboratory reading(s) has/have been documented in the patient's medical records.

**obeticholic acid 5 mg tablet, 30**

| 12630R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,835.98 | 25.00 | Ocaliva [GH] |

**obeticholic acid 10 mg tablet, 30**

| 12640G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,835.98 | 25.00 | Ocaliva [GH] |

## OBETICHOLIC ACID

**Caution** Hepatic decompensation and failure, in some cases fatal, have been reported in post-marketing reports in patients with moderate to severe hepatic impairment when dosed incorrectly.

**Note** Not for use in the treatment of sclerosing cholangitis.

**Note** In accordance with the dosing directions in the approved Product Information, the 10 mg presentation is not PBS listed for initiation of treatment.

**Note** Laboratory readings requested in this authority application must be no older than 52 weeks, prior to starting obeticholic acid or elafibranor, whichever is used first.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17498***

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, **AND**

- Patient must be undergoing concurrent treatment with ursodeoxycholic acid; **OR**
- Patient must be undergoing treatment with this drug as monotherapy because treatment with ursodeoxycholic acid is not tolerated/contraindicated, **AND**
- Patient must not be undergoing concurrent treatment with elafibranor.

**Clinical criteria:**

- Patient must have experienced an inadequate response to ursodeoxycholic acid, despite treatment with ursodeoxycholic acid for at least 52 weeks at a therapeutic dose, prior to initiating treatment with this drug; **OR**
- Patient must have experienced an intolerance/contraindication to ursodeoxycholic acid of a severity requiring permanent treatment discontinuation, prior to initiating treatment with this drug, **AND**
- Patient must not have/be each of: (i) severe liver disease, (ii) immunocompromised, **AND**
- Patient must have an alkaline phosphatase (ALP) level of at least 1.67 times the upper limit of normal (ULN) prior to initiating treatment with this drug, having accounted for each of: (i) age, (ii) gender, (iii) laboratory to laboratory variances in the definition of 'normal', despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; **OR**
- Patient must have a total bilirubin level between 1 to 2 times the ULN prior to initiating treatment with this drug, despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; **OR**
- Patient must have abnormal readings of at least one of: (i) alkaline phosphatase (ii) total bilirubin, in the presence of an intolerance of a severity requiring treatment discontinuation with ursodeoxycholic acid; **OR**
- Patient must have experienced an intolerance to elafibranor of a severity requiring treatment discontinuation, prior to initiating treatment with this drug; **OR**
- Patient must have inadequately responded to treatment with elafibranor, prior to initiating treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Document and retain in the patient's medical records the qualifying baseline laboratory reading for the purpose of assessing response to treatment under the 'Continuing treatment' restriction.

### obeticholic acid 5 mg tablet, 30

12623J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 3,835.98 | 25.00 | Ocaliva [GH] |

## URSODEOXYCHOLIC ACID

**Note** Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

**Authority Required (STREAMLINED)**

***16558***

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

### ursodeoxycholic acid 250 mg capsule, 100

8448P

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 4 | 0.00 | *222.12 | 25.00 | [a] APO-Ursodeoxycholic acid [TX] | [a] Ursodox GH [GQ] |
| | | | | | [a] Ursofalk [FD] | [a] Ursosan [BZ] |

## URSODEOXYCHOLIC ACID

**Note** Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

**Note** Pharmaceutical benefits that have the form ursodeoxycholic acid 500 mg capsule and pharmaceutical benefits that have the form ursodeoxycholic acid 500 mg tablet are equivalent for the purposes of substitution.

**Authority Required (STREAMLINED)**

***16558***

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

### ursodeoxycholic acid 500 mg tablet, 100

11180K

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 4 | 0.00 | 288.63 | 25.00 | [a] ARX-URSODEOXYCHOLIC ACID [XT] | [a] Ursofalk [FD] |

### Ursodeoxycholic acid 500 mg capsule, 100

14716M

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | 0.00 | 288.63 | 25.00 | [a] Ursodox GH [GQ] |

## *Other drugs for bile therapy*

## ELAFIBRANOR

**Caution** Hepatic decompensation and failure, in some cases fatal, have been reported in post-marketing reports in patients with moderate to severe hepatic impairment when dosed incorrectly.

**Note** Not for use in the treatment of sclerosing cholangitis.

**Note** Laboratory readings requested in this authority application must be no older than 52 weeks.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17501***

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; **OR**
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this drug, with treatment having commenced through one of: (i) the 'Initial treatment' listing, (ii) 'Grandfather' arrangements, **AND**
- Patient must be undergoing concurrent treatment with ursodeoxycholic acid; **OR**
- Patient must be undergoing treatment with this drug as monotherapy because treatment with ursodeoxycholic acid is not tolerated/contraindicated, **AND**
- Patient must not be undergoing concurrent treatment with obeticholic acid.

**Clinical criteria:**

- Patient must have achieved an adequate response to this drug, defined as having at least one of: (i) an alkaline phosphate (ALP) level less than 1.67 times the upper limit of normal (ULN), (ii) a reduction in the ALP reading of at least 15% compared to the baseline level provided with the initial authority application, (iii) a total bilirubin level within the normal reference range.

The improvement in the qualifying laboratory reading(s) has/have been documented in the patient's medical records.

### Elafibranor 80 mg tablet, 30

| 15089E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,969.00 | 25.00 | Iqirvo [IS] |

## ELAFIBRANOR

**Caution** Hepatic decompensation and failure, in some cases fatal, have been reported in post-marketing reports in patients with moderate to severe hepatic impairment when dosed incorrectly.

**Note** Not for use in the treatment of sclerosing cholangitis.

**Note** Laboratory readings requested in this authority application must be no older than 52 weeks, prior to starting obeticholic acid or elafibranor, whichever is used first.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17499***

Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, **AND**
- Patient must be undergoing concurrent treatment with ursodeoxycholic acid; **OR**
- Patient must be undergoing treatment with this drug as monotherapy because treatment with ursodeoxycholic acid is not tolerated/contraindicated, **AND**
- Patient must not be undergoing concurrent treatment with obeticholic acid.

**Clinical criteria:**

- Patient must have experienced an inadequate response to ursodeoxycholic acid, despite treatment with ursodeoxycholic acid for at least 52 weeks at a therapeutic dose, prior to initiating treatment with this drug; **OR**
- Patient must have experienced an intolerance/contraindication to ursodeoxycholic acid of a severity requiring permanent treatment discontinuation, prior to initiating treatment with this drug, **AND**
- Patient must not have/be each of: (i) severe liver disease, (ii) immunocompromised, **AND**
- Patient must have an alkaline phosphatase (ALP) level of at least 1.67 times the upper limit of normal (ULN) prior to initiating treatment with this drug, having accounted for each of: (i) age, (ii) gender, (iii) laboratory to laboratory variances in the definition of 'normal', despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; **OR**

- Patient must have a total bilirubin level between 1 to 2 times the ULN prior to initiating treatment with this drug, despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; **OR**
- Patient must have abnormal readings of at least one of: (i) alkaline phosphatase (ii) total bilirubin, in the presence of an intolerance of a severity requiring treatment discontinuation with ursodeoxycholic acid; **OR**
- Patient must have experienced an intolerance to obeticholic acid of a severity requiring treatment discontinuation, prior to initiating treatment with this drug; **OR**
- Patient must have inadequately responded to treatment with obeticholic acid, prior to initiating treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Document and retain in the patient's medical records the qualifying baseline laboratory reading for the purpose of assessing response to treatment under the 'Continuing treatment' restriction.

**Elafibranor 80 mg tablet, 30**

15107D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 5,969.00 | 25.00 | Iqirvo [IS] |

## ODEVIXIBAT

**Note** The recommended dose of odevixibat for initial treatment is 40 micrograms/kg/day. Improvement in pruritus and reduction of serum bile acid levels may occur gradually in some patients after initiating odevixibat therapy.

If an adequate clinical response has been achieved after 3 consecutive months since commencement of treatment, odevixibat should be renewed at 40 micrograms/kg/day through the continuing treatment phase.

**Dose modification (where dose escalation occurs during initial treatment)**

If an adequate clinical response has not been achieved after at least 1 month and up to 3 months of initial treatment, the dose may be increased to 120 micrograms/kg/day (maximum of 7,200 micrograms per day) through the dose modification treatment phase for up to a total period of 6 months from the date of treatment commencement with odevixibat.

If an adequate clinical response is demonstrated following the balance of up to 6 months of treatment at the higher dose of 120 micrograms/kg/day, odevixibat can be renewed at the same dose through the continuing treatment phase.

If a patient fails to demonstrate a response after 6 months of treatment with this drug for this condition (inclusive of initial and dose modification treatment), they will no longer be eligible to receive PBS-subsidised treatment with this drug for this condition.

**Continuing treatment (where dose escalation occurs during continuing treatment)**

If an adequate clinical response is unable to be maintained at the lower dose (40 micrograms/kg/day) during continuing treatment, the dose may be increased to 120 micrograms/kg/day (maximum of 7,200 micrograms per day) through the continuing treatment phase.

If an adequate clinical response is demonstrated at the higher dose of 120 micrograms/kg/day, odevixibat can continue to be renewed at the same dose through the continuing treatment phase.

Patients who are unable to demonstrate an adequate clinical response to continuing treatment at the higher dose will be ineligible for further PBS-subsidised treatment with this drug for this condition.

**Recommencing treatment**

Patients who have demonstrated an adequate clinical response and have ceased treatment for reasons other than a lack of response may recommence treatment through the continuing treatment phase.

**Note** See the following article for details of the Prucision™ ObsRO Pruritus Scale:

Gwaltney C, Ivanescu C, Karlsson L, Warholic N, Kjems L, Horn P. Validation of the PRUCISION instruments in pediatric patients with progressive familial intrahepatic cholestasis. *Adv Ther.* 2022;39(11):5105-5125

The Prucision™ ObsRO Pruritus Scale is available as a downloadable document at:

https://d2rkmuse97gwnh.cloudfront.net/a88aa6d6-3ca0-4362-a711-d53c45ae33ff/f5ea92bf-e36b-421c-a9fe-af77243f0e42/f5ea92bf-e36b-421c-a9fe-af77243f0e42_source__v.docx

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17722***

Progressive familial intrahepatic cholestasis (PFIC)

Treatment Phase: Dose modification (Dose escalation from initial treatment phase; for PFIC diagnosed after turning 18 years of age)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have demonstrated an adequate clinical response after at least 1 month and up to 3 months following commencement of treatment at 40 micrograms/kg/day.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug for this condition at 120 micrograms/kg/day, **AND**
- Must be treated by a specialist hepatologist experienced in the management of progressive familial intrahepatic cholestasis (PFIC); **OR**

- Must be treated by a medical practitioner under the supervision of a specialist experienced in the management of progressive familial intrahepatic cholestasis (PFIC).

At the time of the authority application, the prescriber should request sufficient quantity and repeats to provide for the balance to complete up to 6 months of treatment (inclusive of initial and dose modification treatment), if dose modification is being accessed following initial treatment.

An application for continuing treatment must occur following an assessment of response conducted up to a maximum of 6 months from initiation of therapy. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

If a patient fails to demonstrate a response to treatment 6 months after initiating treatment with this drug for this condition (inclusive of initial and dose modification treatment), they will no longer be eligible to receive PBS-subsidised treatment with this drug for this condition.

An adequate clinical response under this treatment phase is defined as an average of at least 1 grade improvement in pruritus score on the Prucision™ ObsRO Pruritus Scale, assessed on 3 occasions over a one-week period prior to assessment of response.

Confirmation of eligibility for dose modification treatment must be documented in the patient's medical records (include assessment of response score after at least 1 month and up to 3 months after commencing initial treatment).

Any further authority applications occurring immediately after access through this dose modification listing are not to occur through the initial treatment listing.

**Dose modification**

Where the drug's Product Information indicates variable dosing regimens based on the individual's response/tolerance, apply under this listing to continue treatment with the new strength. Mark any remaining repeat prescriptions for the discontinued strength with the word 'cancelled'. This treatment phase listing recognises that a patient's optimal dose may not always be immediately apparent at the time of treatment initiation and therefore does not require confirmation of an objective, adequate response to the preceding supply of drug.

Eligible patients must not be recommencing treatment directly through this treatment phase.

**Odevixibat 200 microgram capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15185F | 12 | 4 | 0.00 | *68,684.52 | 25.00 | Bylvay [IS] |

**Odevixibat 400 microgram capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15184E | 6 | 4 | 0.00 | *68,407.38 | 25.00 | Bylvay [IS] |

**Odevixibat 600 microgram capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15194Q | 12 | 4 | 0.00 | *203,665.32 | 25.00 | Bylvay [IS] |

**Odevixibat 1.2 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15134M | 6 | 4 | 0.00 | *202,327.38 | 25.00 | Bylvay [IS] |

## ODEVIXIBAT

**Note** The recommended dose of odevixibat for initial treatment is 40 micrograms/kg/day. Improvement in pruritus and reduction of serum bile acid levels may occur gradually in some patients after initiating odevixibat therapy.

If an adequate clinical response has been achieved after 3 consecutive months since commencement of treatment, odevixibat should be renewed at 40 micrograms/kg/day through the continuing treatment phase.

**Dose modification (where dose escalation occurs during initial treatment)**

If an adequate clinical response has not been achieved after at least 1 month and up to 3 months of initial treatment, the dose may be increased to 120 micrograms/kg/day (maximum of 7,200 micrograms per day) through the dose modification treatment phase for up to a total period of 6 months from the date of treatment commencement with odevixibat.

If an adequate clinical response is demonstrated following the balance of up to 6 months of treatment at the higher dose of 120 micrograms/kg/day, odevixibat can be renewed at the same dose through the continuing treatment phase.

If a patient fails to demonstrate a response after 6 months of treatment with this drug for this condition (inclusive of initial and dose modification treatment), they will no longer be eligible to receive PBS-subsidised treatment with this drug for this condition.

**Continuing treatment (where dose escalation occurs during continuing treatment)**

If an adequate clinical response is unable to be maintained at the lower dose (40 micrograms/kg/day) during continuing treatment, the dose may be increased to 120 micrograms/kg/day (maximum of 7,200 micrograms per day) through the continuing treatment phase.

If an adequate clinical response is demonstrated at the higher dose of 120 micrograms/kg/day, odevixibat can continue to be renewed at the same dose through the continuing treatment phase.

Patients who are unable to demonstrate an adequate clinical response to continuing treatment at the higher dose will be ineligible for further PBS-subsidised treatment with this drug for this condition.

**Recommencing treatment**

Patients who have demonstrated an adequate clinical response and have ceased treatment for reasons other than a lack of response may recommence treatment through the continuing treatment phase.

**Note** See the following article for details of the Prucision™ ObsRO Pruritus Scale:

Gwaltney C, Ivanescu C, Karlsson L, Warholic N, Kjems L, Horn P. Validation of the PRUCISION instruments in pediatric patients with progressive familial intrahepatic cholestasis. *Adv Ther.* 2022;39(11):5105-5125

The Prucision™ ObsRO Pruritus Scale is available as a downloadable document at:

https://d2rkmuse97gwnh.cloudfront.net/a88aa6d6-3ca0-4362-a711-d53c45ae33ff/f5ea92bf-e36b-421c-a9fe-af77243f0e42/f5ea92bf-e36b-421c-a9fe-af77243f0e42_source__v.docx

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***17701***

Progressive familial intrahepatic cholestasis (PFIC)

Treatment Phase: Initial treatment (PFIC diagnosed prior to turning 18 years of age)

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication, **AND**
- Patient must have a clinical diagnosis of progressive familial intrahepatic cholestasis (PFIC), **AND**
- Patient must have elevated serum bile acids at treatment initiation with this drug, **AND**
- Patient must be experiencing itch at treatment initiation with this drug, with other factors causing pruritus excluded through both: (i) physical examination, (ii) patient history, **AND**
- Patient must have had an average pruritus score of at least 2 on the Prucision™ ObsRO Pruritus Scale assessed on three occasions over a one-week period prior to treatment initiation with this drug.

**Treatment criteria:**

- Must be treated by a specialist experienced in the management of progressive familial intrahepatic cholestasis (PFIC), who is either a: (i) gastroenterologist, (ii) hepatologist.

**Population criteria:**

- Patient must be aged between 6 months and 17 years inclusive; **OR**
- Patient must be/have been diagnosed prior to turning 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pruritus score using the Prucision™ ObsRO Pruritus scale;

(2) details of serum bile acids (date and micromol/L).

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescriber must exclude any other causes of pruritus which include any of the following:

(i) drug related (e.g., opioid-related pruritus);

(ii) drug hypersensitivity or adverse effect; contact dermatitis; allergy;

(iii) differential diagnoses (e.g., xerosis; infestations; iron deficiency; chronic kidney disease; polycythaemia vera/leukaemia/lymphoma; hypothyroidism; uncontrolled diabetes, eczema, scabies).

At the time of the authority application, the prescriber should request the appropriate strength(s) and quantity based on the patient's weight, according to the dosing schedule in the TGA-approved Product Information to provide sufficient drug for one month's supply with 2 repeats. A separate authority approval is required for each strength requested.

An application for continuing treatment must occur following an assessment of response conducted up to 3 months of therapy. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An application for dose modification treatment must occur following an assessment of response conducted from 1 month of therapy up to 3 months of therapy. This will enable ongoing treatment for those who meet the dose modification restriction criteria for PBS-subsidised treatment.

If a patient fails to demonstrate a response to treatment with this drug after 1 month, they will be eligible to receive PBS-subsidised treatment at a higher dose with this drug for this condition under the dose modification treatment phase for a maximum of 5 months; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs within this treatment phase.

All diagnostic reports/tools must be documented in the patient's medical records.

An adequate clinical response to initial treatment is defined as an average of at least 1 grade improvement in pruritus score on the Prucision™ ObsRO Pruritus Scale, assessed on 3 occasions over a one-week period prior to assessment of response.

Eligible patients must not be recommencing treatment directly through this treatment phase.

**Odevixibat 200 microgram capsule, 30**

| 15135N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 12 | 2 | 0.00 | *68,684.52 | 25.00 | Bylvay [IS] |

**Odevixibat 400 microgram capsule, 30**

| 15183D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | 2 | 0.00 | *68,407.38 | 25.00 | Bylvay [IS] |

**Odevixibat 600 microgram capsule, 30**

| 15181B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 12 | 2 | 0.00 | *203,665.32 | 25.00 | Bylvay [IS] |

**Odevixibat 1.2 mg capsule, 30**

| 15182C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | 2 | 0.00 | *202,327.38 | 25.00 | Bylvay [IS] |

## ODEVIXIBAT

**Note** The recommended dose of odevixibat for initial treatment is 40 micrograms/kg/day. Improvement in pruritus and reduction of serum bile acid levels may occur gradually in some patients after initiating odevixibat therapy.

If an adequate clinical response has been achieved after 3 consecutive months since commencement of treatment, odevixibat should be renewed at 40 micrograms/kg/day through the continuing treatment phase.

**Dose modification (where dose escalation occurs during initial treatment)**

If an adequate clinical response has not been achieved after at least 1 month and up to 3 months of initial treatment, the dose may be increased to 120 micrograms/kg/day (maximum of 7,200 micrograms per day) through the dose modification treatment phase for up to a total period of 6 months from the date of treatment commencement with odevixibat.

If an adequate clinical response is demonstrated following the balance of up to 6 months of treatment at the higher dose of 120 micrograms/kg/day, odevixibat can be renewed at the same dose through the continuing treatment phase.

If a patient fails to demonstrate a response after 6 months of treatment with this drug for this condition (inclusive of initial and dose modification treatment), they will no longer be eligible to receive PBS-subsidised treatment with this drug for this condition.

**Continuing treatment (where dose escalation occurs during continuing treatment)**

If an adequate clinical response is unable to be maintained at the lower dose (40 micrograms/kg/day) during continuing treatment, the dose may be increased to 120 micrograms/kg/day (maximum of 7,200 micrograms per day) through the continuing treatment phase.

If an adequate clinical response is demonstrated at the higher dose of 120 micrograms/kg/day, odevixibat can continue to be renewed at the same dose through the continuing treatment phase.

Patients who are unable to demonstrate an adequate clinical response to continuing treatment at the higher dose will be ineligible for further PBS-subsidised treatment with this drug for this condition.

**Recommencing treatment**

Patients who have demonstrated an adequate clinical response and have ceased treatment for reasons other than a lack of response may recommence treatment through the continuing treatment phase.

**Note** See the following article for details of the Prucision™ ObsRO Pruritus Scale:

Gwaltney C, Ivanescu C, Karlsson L, Warholic N, Kjems L, Horn P. Validation of the PRUCISION instruments in pediatric patients with progressive familial intrahepatic cholestasis. *Adv Ther.* 2022;39(11):5105-5125

The Prucision™ ObsRO Pruritus Scale is available as a downloadable document at:

https://d2rkmuse97gwnh.cloudfront.net/a88aa6d6-3ca0-4362-a711-d53c45ae33ff/f5ea92bf-e36b-421c-a9fe-af77243f0e42/f5ea92bf-e36b-421c-a9fe-af77243f0e42_source__v.docx

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17721***

Progressive familial intrahepatic cholestasis (PFIC)

Treatment Phase: Continuing treatment (PFIC diagnosed after turning 18 years of age)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate clinical response to the most recent course of treatment; **OR**
- Patient must be undergoing dose escalation to 120 micrograms/kg/day if they were unable to maintain a previously demonstrated adequate clinical response at 40 micrograms/kg/day in continuing treatment, **AND**

- Patient must not be undergoing treatment with this drug for this condition, where an adequate clinical response was unable to be maintained at 120 micrograms/kg/day.

**Treatment criteria:**

- Must be treated by a specialist hepatologist experienced in the management of progressive familial intrahepatic cholestasis (PFIC); **OR**
- Must be treated by a medical practitioner under the supervision of a specialist experienced in the management of progressive familial intrahepatic cholestasis (PFIC).

An adequate clinical response under this treatment phase is defined as an average of at least 1 grade improvement in pruritus score on the Prucision™ ObsRO Pruritus Scale, assessed on 3 occasions over a one-week period prior to assessment of response.

Confirmation of eligibility for continuing treatment must be provided with the authority application and documented in the patient's medical records (include assessment of adequate clinical response to preceding supply).

A patient may be eligible for treatment at the higher dose (120 micrograms/kg/day), if a loss of response occurred, or if an adequate response was unable to be maintained at the lower dose (40 micrograms/kg/day) during continuing treatment. To be eligible for continuing treatment at the higher dose (120 micrograms/kg/day), the patient must demonstrate and maintain an adequate clinical response at the higher dose.

**Odevixibat 200 microgram capsule, 30**

| 15136P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 12 | 5 | 0.00 | *68,684.52 | 25.00 | Bylvay [IS] |

**Odevixibat 400 microgram capsule, 30**

| 15174P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | 5 | 0.00 | *68,407.38 | 25.00 | Bylvay [IS] |

**Odevixibat 600 microgram capsule, 30**

| 15164D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 12 | 5 | 0.00 | *203,665.32 | 25.00 | Bylvay [IS] |

**Odevixibat 1.2 mg capsule, 30**

| 15150J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | 5 | 0.00 | *202,327.38 | 25.00 | Bylvay [IS] |

## ODEVIXIBAT

**Note** The recommended dose of odevixibat for initial treatment is 40 micrograms/kg/day. Improvement in pruritus and reduction of serum bile acid levels may occur gradually in some patients after initiating odevixibat therapy.

If an adequate clinical response has been achieved after 3 consecutive months since commencement of treatment, odevixibat should be renewed at 40 micrograms/kg/day through the continuing treatment phase.

**Dose modification (where dose escalation occurs during initial treatment)**

If an adequate clinical response has not been achieved after at least 1 month and up to 3 months of initial treatment, the dose may be increased to 120 micrograms/kg/day (maximum of 7,200 micrograms per day) through the dose modification treatment phase for up to a total period of 6 months from the date of treatment commencement with odevixibat.

If an adequate clinical response is demonstrated following the balance of up to 6 months of treatment at the higher dose of 120 micrograms/kg/day, odevixibat can be renewed at the same dose through the continuing treatment phase.

If a patient fails to demonstrate a response after 6 months of treatment with this drug for this condition (inclusive of initial and dose modification treatment), they will no longer be eligible to receive PBS-subsidised treatment with this drug for this condition.

**Continuing treatment (where dose escalation occurs during continuing treatment)**

If an adequate clinical response is unable to be maintained at the lower dose (40 micrograms/kg/day) during continuing treatment, the dose may be increased to 120 micrograms/kg/day (maximum of 7,200 micrograms per day) through the continuing treatment phase.

If an adequate clinical response is demonstrated at the higher dose of 120 micrograms/kg/day, odevixibat can continue to be renewed at the same dose through the continuing treatment phase.

Patients who are unable to demonstrate an adequate clinical response to continuing treatment at the higher dose will be ineligible for further PBS-subsidised treatment with this drug for this condition.

**Recommencing treatment**

Patients who have demonstrated an adequate clinical response and have ceased treatment for reasons other than a lack of response may recommence treatment through the continuing treatment phase.

**Note** See the following article for details of the Prucision™ ObsRO Pruritus Scale:

Gwaltney C, Ivanescu C, Karlsson L, Warholic N, Kjems L, Horn P. Validation of the PRUCISION instruments in pediatric patients with progressive familial intrahepatic cholestasis. *Adv Ther.* 2022;39(11):5105-5125

The Prucision™ ObsRO Pruritus Scale is available as a downloadable document at:

https://d2rkmuse97gwnh.cloudfront.net/a88aa6d6-3ca0-4362-a711-d53c45ae33ff/f5ea92bf-e36b-421c-a9fe-af77243f0e42/f5ea92bf-e36b-421c-a9fe-af77243f0e42_source__v.docx

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**

***17705***

Progressive familial intrahepatic cholestasis (PFIC)

Treatment Phase: Continuing treatment (PFIC diagnosed prior to turning 18 years of age)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate clinical response to the most recent course of treatment; **OR**
- Patient must be undergoing dose escalation to 120 micrograms/kg/day if they were unable to maintain a previously demonstrated adequate clinical response at 40 micrograms/kg/day in continuing treatment, **AND**
- Patient must not be undergoing treatment with this drug for this condition, where an adequate clinical response was unable to be maintained at 120 micrograms/kg/day.

**Treatment criteria:**

- Must be treated by a specialist experienced in the management of progressive familial intrahepatic cholestasis (PFIC), who is either a: (i) gastroenterologist, (ii) hepatologist; **OR**
- Must be treated by a medical practitioner under the supervision of a specialist experienced in the management of progressive familial intrahepatic cholestasis (PFIC).

An adequate clinical response under this treatment phase is defined as an average of at least 1 grade improvement in pruritus score on the Prucision™ ObsRO Pruritus Scale, assessed on 3 occasions over a one-week period prior to assessment of response.

Confirmation of eligibility for continuing treatment must be provided with the authority application and documented in the patient's medical records (include assessment of adequate clinical response to preceding supply).

A patient may be eligible for treatment at the higher dose (120 micrograms/kg/day), if a loss of response occurred, or if an adequate response was unable to be maintained at the lower dose (40 micrograms/kg/day) during continuing treatment. To be eligible for continuing treatment at the higher dose (120 micrograms/kg/day), the patient must demonstrate and maintain an adequate clinical response at the higher dose.

**Odevixibat 200 microgram capsule, 30**

| 15195R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 12 | 5 | 0.00 | *68,684.52 | 25.00 | Bylvay [IS] |

**Odevixibat 400 microgram capsule, 30**

| 15151K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | 5 | 0.00 | *68,407.38 | 25.00 | Bylvay [IS] |

**Odevixibat 600 microgram capsule, 30**

| 15158T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 12 | 5 | 0.00 | *203,665.32 | 25.00 | Bylvay [IS] |

**Odevixibat 1.2 mg capsule, 30**

| 15165E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | 5 | 0.00 | *202,327.38 | 25.00 | Bylvay [IS] |

## ODEVIXIBAT

**Note** The recommended dose of odevixibat for initial treatment is 40 micrograms/kg/day. Improvement in pruritus and reduction of serum bile acid levels may occur gradually in some patients after initiating odevixibat therapy.

If an adequate clinical response has been achieved after 3 consecutive months since commencement of treatment, odevixibat should be renewed at 40 micrograms/kg/day through the continuing treatment phase.

**Dose modification (where dose escalation occurs during initial treatment)**

If an adequate clinical response has not been achieved after at least 1 month and up to 3 months of initial treatment, the dose may be increased to 120 micrograms/kg/day (maximum of 7,200 micrograms per day) through the dose modification treatment phase for up to a total period of 6 months from the date of treatment commencement with odevixibat.

If an adequate clinical response is demonstrated following the balance of up to 6 months of treatment at the higher dose of 120 micrograms/kg/day, odevixibat can be renewed at the same dose through the continuing treatment phase.

If a patient fails to demonstrate a response after 6 months of treatment with this drug for this condition (inclusive of initial and dose modification treatment), they will no longer be eligible to receive PBS-subsidised treatment with this drug for this condition.

**Continuing treatment (where dose escalation occurs during continuing treatment)**

If an adequate clinical response is unable to be maintained at the lower dose (40 micrograms/kg/day) during continuing treatment, the dose may be increased to 120 micrograms/kg/day (maximum of 7,200 micrograms per day) through the continuing treatment phase.

If an adequate clinical response is demonstrated at the higher dose of 120 micrograms/kg/day, odevixibat can continue to be renewed at the same dose through the continuing treatment phase.

Patients who are unable to demonstrate an adequate clinical response to continuing treatment at the higher dose will be ineligible for further PBS-subsidised treatment with this drug for this condition.

**Recommencing treatment**

Patients who have demonstrated an adequate clinical response and have ceased treatment for reasons other than a lack of response may recommence treatment through the continuing treatment phase.

**Note** See the following article for details of the Prucision™ ObsRO Pruritus Scale:

Gwaltney C, Ivanescu C, Karlsson L, Warholic N, Kjems L, Horn P. Validation of the PRUCISION instruments in pediatric patients with progressive familial intrahepatic cholestasis. *Adv Ther.* 2022;39(11):5105-5125

The Prucision™ ObsRO Pruritus Scale is available as a downloadable document at:

https://d2rkmuse97gwnh.cloudfront.net/a88aa6d6-3ca0-4362-a711-d53c45ae33ff/f5ea92bf-e36b-421c-a9fe-af77243f0e42/f5ea92bf-e36b-421c-a9fe-af77243f0e42_source__v.docx

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***17703***

Progressive familial intrahepatic cholestasis (PFIC)

Treatment Phase: Initial treatment (PFIC diagnosed after turning 18 years of age)

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication, **AND**
- Patient must have a clinical diagnosis of progressive familial intrahepatic cholestasis (PFIC), **AND**
- Patient must have elevated serum bile acids at treatment initiation with this drug, **AND**
- Patient must be experiencing itch at treatment initiation with this drug, with other factors causing pruritus excluded through both: (i) physical examination, (ii) patient history, **AND**
- Patient must have had an average pruritus score of at least 2 on the Prucision™ ObsRO Pruritus Scale assessed on three occasions over a one-week period prior to treatment initiation with this drug.

**Treatment criteria:**

- Must be treated by a specialist hepatologist experienced in the management of progressive familial intrahepatic cholestasis (PFIC).

**Population criteria:**

- Patient must be/have been diagnosed after turning 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pruritus score using the Prucision™ ObsRO Pruritus scale;

(2) details of serum bile acids (date and micromol/L).

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescriber must exclude any other causes of pruritus which include any of the following:

(i) drug related (e.g., opioid-related pruritus);

(ii) drug hypersensitivity or adverse effect; contact dermatitis; allergy;

(iii) differential diagnoses (e.g., xerosis; infestations; iron deficiency; chronic kidney disease; polycythaemia vera/leukaemia/lymphoma; hypothyroidism; uncontrolled diabetes, eczema, scabies).

At the time of the authority application, the prescriber should request the appropriate strength(s) and quantity based on the patient's weight, according to the dosing schedule in the TGA-approved Product Information to provide sufficient drug for one month's supply with 2 repeats. A separate authority approval is required for each strength requested.

An application for continuing treatment must occur following an assessment of response conducted up to 3 months of therapy. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An application for dose modification treatment must occur following an assessment of response conducted from 1 month of therapy up to 3 months of therapy. This will enable ongoing treatment for those who meet the dose modification restriction criteria for PBS-subsidised treatment.

If a patient fails to demonstrate a response to treatment with this drug after 1 month, they will be eligible to receive PBS-subsidised treatment at a higher dose with this drug for this condition under the dose modification treatment phase for a maximum of 5 months; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs within this treatment phase.

All diagnostic reports/tools must be documented in the patient's medical records.

An adequate clinical response to initial treatment is defined as an average of at least 1 grade improvement in pruritus score on the Prucision™ ObsRO Pruritus Scale, assessed on 3 occasions over a one-week period prior to assessment of response.

Eligible patients must not be recommencing treatment directly through this treatment phase.

**Odevixibat 200 microgram capsule, 30**

| 15157R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 12 | 2 | 0.00 | *68,684.52 | 25.00 | Bylvay [IS] |

**Odevixibat 400 microgram capsule, 30**

| 15186G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | 2 | 0.00 | *68,407.38 | 25.00 | Bylvay [IS] |

**Odevixibat 600 microgram capsule, 30**

| 15166F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 12 | 2 | 0.00 | *203,665.32 | 25.00 | Bylvay [IS] |

**Odevixibat 1.2 mg capsule, 30**

| 15196T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | 2 | 0.00 | *202,327.38 | 25.00 | Bylvay [IS] |

## ODEVIXIBAT

**Note** The recommended dose of odevixibat for initial treatment is 40 micrograms/kg/day. Improvement in pruritus and reduction of serum bile acid levels may occur gradually in some patients after initiating odevixibat therapy.

If an adequate clinical response has been achieved after 3 consecutive months since commencement of treatment, odevixibat should be renewed at 40 micrograms/kg/day through the continuing treatment phase.

**Dose modification (where dose escalation occurs during initial treatment)**

If an adequate clinical response has not been achieved after at least 1 month and up to 3 months of initial treatment, the dose may be increased to 120 micrograms/kg/day (maximum of 7,200 micrograms per day) through the dose modification treatment phase for up to a total period of 6 months from the date of treatment commencement with odevixibat.

If an adequate clinical response is demonstrated following the balance of up to 6 months of treatment at the higher dose of 120 micrograms/kg/day, odevixibat can be renewed at the same dose through the continuing treatment phase.

If a patient fails to demonstrate a response after 6 months of treatment with this drug for this condition (inclusive of initial and dose modification treatment), they will no longer be eligible to receive PBS-subsidised treatment with this drug for this condition.

**Continuing treatment (where dose escalation occurs during continuing treatment)**

If an adequate clinical response is unable to be maintained at the lower dose (40 micrograms/kg/day) during continuing treatment, the dose may be increased to 120 micrograms/kg/day (maximum of 7,200 micrograms per day) through the continuing treatment phase.

If an adequate clinical response is demonstrated at the higher dose of 120 micrograms/kg/day, odevixibat can continue to be renewed at the same dose through the continuing treatment phase.

Patients who are unable to demonstrate an adequate clinical response to continuing treatment at the higher dose will be ineligible for further PBS-subsidised treatment with this drug for this condition.

**Recommencing treatment**

Patients who have demonstrated an adequate clinical response and have ceased treatment for reasons other than a lack of response may recommence treatment through the continuing treatment phase.

**Note** See the following article for details of the Prucision™ ObsRO Pruritus Scale:

Gwaltney C, Ivanescu C, Karlsson L, Warholic N, Kjems L, Horn P. Validation of the PRUCISION instruments in pediatric patients with progressive familial intrahepatic cholestasis. *Adv Ther.* 2022;39(11):5105-5125

The Prucision™ ObsRO Pruritus Scale is available as a downloadable document at:

https://d2rkmuse97gwnh.cloudfront.net/a88aa6d6-3ca0-4362-a711-d53c45ae33ff/f5ea92bf-e36b-421c-a9fe-af77243f0e42/f5ea92bf-e36b-421c-a9fe-af77243f0e42_source__v.docx

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17738***

Progressive familial intrahepatic cholestasis (PFIC)

Treatment Phase: Dose modification (Dose escalation from initial treatment phase; for PFIC diagnosed prior to turning 18 years of age)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have demonstrated an adequate clinical response after at least 1 month and up to 3 months following commencement of treatment at 40 micrograms/kg/day.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug for this condition at 120 micrograms/kg/day, **AND**
- Must be treated by a specialist experienced in the management of progressive familial intrahepatic cholestasis (PFIC), who is either a: (i) gastroenterologist, (ii) hepatologist; **OR**
- Must be treated by a medical practitioner under the supervision of a specialist experienced in the management of progressive familial intrahepatic cholestasis (PFIC).

At the time of the authority application, the prescriber should request sufficient quantity and repeats to provide for the balance to complete up to 6 months of treatment (inclusive of initial and dose modification treatment), if dose modification is being accessed following initial treatment.

An application for continuing treatment must occur following an assessment of response conducted up to a maximum of 6 months from initiation of therapy. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

If a patient fails to demonstrate a response to treatment 6 months after initiating treatment with this drug for this condition (inclusive of initial and dose modification treatment), they will no longer be eligible to receive PBS-subsidised treatment with this drug for this condition.

An adequate clinical response under this treatment phase is defined as an average of at least 1 grade improvement in pruritus score on the Prucision™ ObsRO Pruritus Scale, assessed on 3 occasions over a one-week period prior to assessment of response.

Confirmation of eligibility for dose modification treatment must be documented in the patient's medical records (include assessment of response score after at least 1 month and up to 3 months after commencing initial treatment).

Any further authority applications occurring immediately after access through this dose modification listing are not to occur through the initial treatment listing.

**Dose modification**

Where the drug's Product Information indicates variable dosing regimens based on the individual's response/tolerance, apply under this listing to continue treatment with the new strength. Mark any remaining repeat prescriptions for the discontinued strength with the word 'cancelled'. This treatment phase listing recognises that a patient's optimal dose may not always be immediately apparent at the time of treatment initiation and therefore does not require confirmation of an objective, adequate response to the preceding supply of drug.

Eligible patients must not be recommencing treatment directly through this treatment phase.

**Odevixibat 200 microgram capsule, 30**

| 15192N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 12 | 4 | 0.00 | *68,684.52 | 25.00 | Bylvay [IS] |

**Odevixibat 400 microgram capsule, 30**

| 15167G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | 4 | 0.00 | *68,407.38 | 25.00 | Bylvay [IS] |

**Odevixibat 600 microgram capsule, 30**

| 15193P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 12 | 4 | 0.00 | *203,665.32 | 25.00 | Bylvay [IS] |

**Odevixibat 1.2 mg capsule, 30**

| 15163C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 6 | 4 | 0.00 | *202,327.38 | 25.00 | Bylvay [IS] |

# DRUGS FOR CONSTIPATION

## DRUGS FOR CONSTIPATION

### *Contact laxatives*

### BISACODYL

**Restricted benefit**

***5640***

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

***5775***

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

***5879***

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

***5819***

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

***5851***

Terminal malignant neoplasia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

***5823***

Anorectal congenital abnormalities

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**

***5866***

Megacolon

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

### bisacodyl 10 mg suppository, 12

1258F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 4 | 0.00 | *25.59 | 25.00 | Petrus Bisacodyl Suppositories [PP] |

NP

### bisacodyl 10 mg suppository, 10

1260H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 5 | 0.00 | *26.85 | 25.00 | [a] Petrus Bisacodyl Suppositories [PP] | |
| | | [B]1.20 | *28.05 | 25.00 | [a] Dulcolax [VZ] | |

NP

## BISACODYL

**Restricted benefit**

***5640***

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

***5720***

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

***5613***

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

***5775***

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

***5776***

Terminal malignant neoplasia

**Restricted benefit**

***5685***

Anorectal congenital abnormalities

**Restricted benefit**
***5804***
Megacolon

**bisacodyl 5 mg enteric tablet, 200**

| 1259G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 20.61 | 22.15 | Lax-Tab [AE] |

## BISACODYL

**Restricted benefit**
***15585***
Constipation
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**
***15586***
Constipation
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

**Restricted benefit**
***15708***
Constipation
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Population criteria:**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**
***15587***
Constipation
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Population criteria:**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**
***15535***
Terminal malignant neoplasia
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**
***15726***
Anorectal congenital abnormalities
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Restricted benefit**
***15727***
Megacolon
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

### bisacodyl 10 mg suppository, 12

| 14305X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 6 | 4 | 0.00 | *36.78 | 25.00 | Petrus Bisacodyl Suppositories [PP] |

### bisacodyl 10 mg suppository, 10

| 14447J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | 0.00 | *39.30 | 25.00 | [a] Petrus Bisacodyl Suppositories [PP] | |
| | | | [B]2.40 | *41.70 | 25.00 | [a] Dulcolax [VZ] | |

## BISACODYL

**Restricted benefit**

***15585***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

***15734***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

***15629***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

***15586***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

**Restricted benefit**

***15572***

Terminal malignant neoplasia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

***15707***

Anorectal congenital abnormalities

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

***15735***

Megacolon

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**bisacodyl 5 mg enteric tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14446H NP | 2 | 2 | 0.00 | *26.86 | 25.00 | Lax-Tab [AE] |

## *Osmotically acting laxatives*

### MACROGOL-3350

**Restricted benefit**

***4171***

Constipation

**Clinical criteria:**

- Patient must have malignant neoplasia.

**Restricted benefit**

***4180***

Constipation

**Clinical criteria:**

- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

**Restricted benefit**

***4179***

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

***4173***

Chronic constipation

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**

***4177***

Faecal impaction

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**macrogol-3350 1 g/g powder for oral liquid, 510 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3416T NP | ‡1 | 5 | 0.00 | 23.55 | 25.00 | OsmoLax [KY] |

### MACROGOL-3350

**Restricted benefit**

***15729***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have malignant neoplasia.

**Restricted benefit**

***15661***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

**Restricted benefit**

***15593***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

**Restricted benefit**

***15539***

Chronic constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Restricted benefit**

***15709***

Faecal impaction

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

### macrogol-3350 1 g/g powder for oral liquid, 510 g

14341T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡2 | 5 | 0.00 | *32.74 | 25.00 | OsmoLax [KY] |

NP

## MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE

**Authority Required (STREAMLINED)**

***18229***

Constipation

**Clinical criteria:**

- Patient must have malignant neoplasia.

**Authority Required (STREAMLINED)**

***18312***

Constipation

**Clinical criteria:**

- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

**Authority Required (STREAMLINED)**

***18414***

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Authority Required (STREAMLINED)**

***18374***

Chronic constipation

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Authority Required (STREAMLINED)**

***18415***

Faecal impaction

**Clinical criteria:**

- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

### macrogol-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets

8612G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | 0.00 | 27.86 | 25.00 | [a] APOHEALTH Macrogol with Electrolytes [GX] | [a] APO-MACROGOL plus ELECTROLYTES [TX] |
| | | | | | [a] Chemists' Own Constipation Relief with electrolytes [OW] | [a] Macrovic [RF] |

NP

## MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE

**Authority Required (STREAMLINED)**

***18416***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have malignant neoplasia.

**Authority Required (STREAMLINED)**

***18375***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**

- The condition must be unresponsive to other oral therapies.

**Authority Required (STREAMLINED)**

***18313***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

**Authority Required (STREAMLINED)**

***18314***

Chronic constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

**Authority Required (STREAMLINED)**

***18376***

Faecal impaction

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

### macrogol-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets

| 14408H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *41.36 | 25.00 | [a] APOHEALTH Macrogol with Electrolytes [GX] | [a] APO-MACROGOL plus ELECTROLYTES [TX] |
| | | | | | | [a] Chemists' Own Constipation Relief with electrolytes [OW] | [a] Macrovic [RF] |

## *Enemas*

### CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL

**Restricted benefit**

***5640***

Constipation

**Clinical criteria:**

- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

***5720***

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

***5613***

Constipation

**Clinical criteria:**

- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

***5775***

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**Restricted benefit**

***5776***

Terminal malignant neoplasia

**Restricted benefit**

***5685***

Anorectal congenital abnormalities

**Restricted benefit**

***5804***

Megacolon

**sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL**

| 2091C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *37.38 | 25.00 | Micolette [AE] |

## CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL

**Restricted benefit**

***15585***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

**Restricted benefit**

***15734***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

**Restricted benefit**

***15629***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

**Restricted benefit**

***15586***

Constipation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

**Restricted benefit**

***15572***

Terminal malignant neoplasia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

***15707***

Anorectal congenital abnormalities

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

***15735***

Megacolon

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL**

| 14534Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *60.40 | 25.00 | Micolette [AE] |

# ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

## INTESTINAL ANTIINFECTIVES

### *Antibiotics*

## NYSTATIN

**nystatin 500 000 units tablet, 50**

| 1696G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 23.75 | 25.00 | Nilstat [AS] |

**nystatin 500 000 units tablet, 50**

| 3342X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 23.75 | 25.00 | Nilstat [AS] |

**nystatin 500 000 units capsule, 50**

| 1699K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 23.75 | 25.00 | Nilstat [AS] |

**nystatin 500 000 units capsule, 50**

| 3345C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 23.75 | 25.00 | Nilstat [AS] |

## RIFAXIMIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**
***4306***
Prevention of hepatic encephalopathy
**Treatment criteria:**
- Must be treated by a gastroenterologist or hepatologist or in consultation with a gastroenterologist or hepatologist.

**Clinical criteria:**
- The treatment must be in combination with lactulose, if lactulose is tolerated, **AND**
- Patient must have had prior episodes of hepatic encephalopathy.

**rifaximin 550 mg tablet, 56**

| 10001J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 441.00 | 25.00 | Xifaxan [NE] |

## VANCOMYCIN

**Note** Metronidazole has similar efficacy to vancomycin but may have less selective pressure to vancomycin resistant enterococci and is therefore the preferred treatment.

**Authority Required**
***5660***
Antibiotic associated pseudomembranous colitis
**Clinical criteria:**
- The condition must be due to Clostridium difficile, **AND**
- The condition must be unresponsive to metronidazole.

**Authority Required**
***5636***
Antibiotic associated pseudomembranous colitis
**Clinical criteria:**
- The condition must be due to Clostridium difficile, **AND**
- Patient must have an intolerance to metronidazole.

**vancomycin 125 mg capsule, 20**

| 3113W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *96.12 | 25.00 | [a] Vancocin [AS] | [a] Vancomycin BNM 125mg [BZ] |
| | | | | | | [a] VANCOR [CR] | |

**vancomycin 250 mg capsule, 20**

| 3114X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *181.00 | 25.00 | [a] Vancocin [AS] | [a] Vancomycin BNM 250mg [BZ] |
| | | | | | | [a] VANCOR [CR] | |

# ELECTROLYTES WITH CARBOHYDRATES

### *Oral rehydration salt formulations*

## SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE + CITRIC ACID

**Restricted benefit**

***5889***
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3196F NP | ‡1 | 0 | 0.00 | 19.07 | 20.61 | O.R.S. [XT] |

## SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE + CITRIC ACID

**Authority Required**
***6786***
Rehydration in intestinal failure

**sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11049M | 30 | 0 | 0.00 | *157.74 | 25.00 | O.R.S. [XT] |

# ANTIPROPULSIVES

## *Antipropulsives*

## DIPHENOXYLATE + ATROPINE SULFATE

**diphenoxylate hydrochloride 2.5 mg + atropine sulfate monohydrate 25 microgram tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2501P NP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Lofenoxal [IL] | |
| | | | [B]3.31 | 20.41 | 18.64 | [a] Lomotil [IM] | |

## LOPERAMIDE

**Authority Required (STREAMLINED)**
***6364***
Diarrhoea
**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**loperamide hydrochloride 2 mg capsule, 12**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1571Q NP | 1 | 0 | 0.00 | 15.99 | 17.53 | [a] Gastrex [CR] | [a] Gastro-Stop [AS] |

## LOPERAMIDE

**Authority Required**
***6343***
Diarrhoea

**loperamide hydrochloride 2 mg capsule, 12**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10889D NP | 5 | 0 | 0.00 | *22.49 | 24.03 | [a] Gastrex [CR] | [a] Gastro-Stop [AS] |

# INTESTINAL ANTIINFLAMMATORY AGENTS

## *Corticosteroids acting locally*

## BUDESONIDE

**Restricted benefit**
***16524***
For prescribing by certain health practitioners
**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**budesonide 2 mg/application foam, 2 x 14 applications**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10034D NP | 1 | 3 | 0.00 | 148.52 | 25.00 | Budenofalk [FD] |

## BUDESONIDE

**Authority Required (STREAMLINED)**
***16674***
Mild to moderate Crohn disease
**Clinical criteria:**

- The condition must affect the ileum; **OR**
- The condition must affect the ascending colon; **OR**
- The condition must affect the ileum and ascending colon.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

The total duration of therapy should be no more than 12 weeks in any single course.

**budesonide 3 mg modified release capsule, 90**

| 12915R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 54.88 | 25.00 | Entocort [EU] |

## BUDESONIDE

**Authority Required (STREAMLINED)**

***16695***

Mild to moderate Crohn disease

**Clinical criteria:**

- The condition must affect the ileum; **OR**
- The condition must affect the ascending colon; **OR**
- The condition must affect the ileum and ascending colon.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

The total duration of therapy should be no more than 10 weeks in any single course.

**budesonide 3 mg enteric capsule, 50**

| 14571X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *66.88 | 25.00 | Budenofalk [FD] |

## BUDESONIDE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17406***

Eosinophilic oesophagitis

Treatment Phase: Subsequent continuing treatment - Maintenance of remission

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have documented evidence of having achieved histologic remission while receiving Initial and First continuing PBS-subsidised treatment with this drug for this condition, defined as a peak eosinophil count of less than 5 eosinophils per high power field (hpf), corresponding to less than 16 eosinophils per $mm^2$ hpf on oesophageal biopsy, **AND**
- The condition must not have progressed while being treated with this drug.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) a prescriber who is not any of the aforementioned prescriber types, but who has consulted at least one of the aforementioned prescriber types.

Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).

The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment.

The result of the histological assessment must be documented in the patient's medical records.

First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.

**budesonide 500 microgram orally disintegrating tablet, 60**

| 12987M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 403.61 | 25.00 | Jorveza [FD] |

**budesonide 1 mg orally disintegrating tablet, 60**

| 12982G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 403.61 | 25.00 | Jorveza [FD] |

## BUDESONIDE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***14608***

Eosinophilic oesophagitis

Treatment Phase: Initial treatment - Induction of remission

**Clinical criteria:**

- Patient must have a history of symptoms of oesophageal dysfunction, **AND**
- Patient must have eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy confirming the presence of at least 15 eosinophils in at least one high power field (hpf); corresponding to approximately 60 eosinophils per $mm^2$ hpf, **AND**
- Patient must not receive more than 90 days of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis.

Applications for treatment of this condition must be received within 12 weeks of biopsy.

Symptoms of oesophageal dysfunction include at least one of the following: dysphasia, odynophagia, transient or self-cleared food impaction, chest pain, epigastric discomfort, vomiting/regurgitation.

Diagnostic sensitivity increases with the number of biopsies and can be optimised, where necessary, by taking at least eight biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).

After prescribing the Initial induction treatment with budesonide, a histologic assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing therapy.

The histologic assessment should be conducted no later than 2 weeks prior to completing the PBS-subsidised First continuing maintenance treatment course to avoid an interruption of supply for continuing therapy.

**budesonide 1 mg orally disintegrating tablet, 90**

| 12994X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 600.74 | 25.00 | Jorveza [FD] |

## BUDESONIDE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17409***

Eosinophilic oesophagitis

Treatment Phase: First continuing treatment - until remission is confirmed

**Clinical criteria:**

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 36 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) a prescriber who is not any of the aforementioned prescriber types, but who has consulted at least one of the aforementioned prescriber types.

Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).

The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment.

The result of the histological assessment must be documented in the patient's medical records.

First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.

**budesonide 500 microgram orally disintegrating tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13719C NP | 1 | 8 | 0.00 | 403.61 | 25.00 | Jorveza [FD] |

**budesonide 1 mg orally disintegrating tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13711P NP | 1 | 8 | 0.00 | 403.61 | 25.00 | Jorveza [FD] |

## PREDNISOLONE SODIUM PHOSPHATE

**Restricted benefit**

***16524***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1920C NP | 4 | 3 | 0.00 | *178.20 | 25.00 | Predsol [AS] |

## PREDNISOLONE SODIUM PHOSPHATE

**Restricted benefit**

***16673***

Proctitis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

***16552***

Ulcerative colitis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**prednisolone (as sodium phosphate) 5 mg suppository, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2554K NP | 3 | 3 | 0.00 | *40.83 | 25.00 | Predsol [AS] |

### *Aminosalicylic acid and similar agents*

## BALSALAZIDE

**Note** Not for the treatment of Crohn disease

**Authority Required (STREAMLINED)**

***16658***

Ulcerative colitis

**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; **OR**
- Patient must be intolerant to sulfasalazine.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**balsalazide sodium 750 mg capsule, 280**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11351K NP | 1 | 5 | 0.00 | 154.84 | 25.00 | Colazide [PK] |

## BALSALAZIDE

**Note** Not for the treatment of Crohn disease

**Authority Required (STREAMLINED)**

***16551***

Ulcerative colitis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had a documented hypersensitivity reaction to a sulphonamide; **OR**
- Patient must be intolerant to sulfasalazine.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### balsalazide sodium 750 mg capsule, 280

| 13484Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *300.32 | 25.00 | Colazide [PK] |

## MESALAZINE

**Note** Not for the treatment of Crohn disease

**Restricted benefit**

***16552***

Ulcerative colitis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### mesalazine 500 mg modified release granules, 100 sachets

| 8598M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *120.58 | 25.00 | Salofalk [FD] |

### mesalazine 800 mg enteric tablet, 90

| 11210B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 78.05 | 25.00 | Asacol [EU] |

### mesalazine 1 g modified release granules, 100 sachets

| 8599N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 113.39 | 25.00 | Salofalk [FD] |

### mesalazine 1.5 g modified release granules, 60 sachets

| 9206M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 99.92 | 25.00 | Salofalk [FD] |

### mesalazine 1.6 g enteric tablet, 60

| 12463Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *150.24 | 25.00 | Asacol [EU] |

### mesalazine 3 g modified release granules, 30 sachets

| 10257W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 99.92 | 25.00 | Salofalk [FD] |

### mesalazine 4 g modified release granules, 30 sachets

| 10254Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 126.66 | 25.00 | Pentasa [FP] |

## MESALAZINE

**Note** Not for the treatment of Crohn disease

**Restricted benefit**

***16491***

Ulcerative colitis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**mesalazine 500 mg modified release granules, 100 sachets**

| 13361F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *231.80 | 25.00 | Salofalk [FD] |

**mesalazine 800 mg enteric tablet, 90**

| 13422K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *143.10 | 25.00 | Asacol [EU] |

**mesalazine 1 g modified release granules, 100 sachets**

| 13398E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *217.32 | 25.00 | Salofalk [FD] |

**mesalazine 1.5 g modified release granules, 60 sachets**

| 13460K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *189.04 | 25.00 | Salofalk [FD] |

**mesalazine 1.6 g enteric tablet, 60**

| 13395B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 4 | 0.00 | *291.12 | 25.00 | Asacol [EU] |

**mesalazine 3 g modified release granules, 30 sachets**

| 13518L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *189.04 | 25.00 | Salofalk [FD] |

**mesalazine 4 g modified release granules, 30 sachets**

| 13456F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *243.96 | 25.00 | Pentasa [FP] |

## MESALAZINE

**Restricted benefit**

***16552***

Ulcerative colitis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

***16490***

Crohn disease

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**mesalazine 250 mg enteric tablet, 100**

| 1611T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 45.06 | 25.00 | Mesasal [GO] |

**mesalazine 500 mg modified release tablet, 100**

| 2214M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *120.58 | 25.00 | Pentasa [FP] |

**mesalazine 500 mg enteric tablet, 100**

| 8731M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *120.58 | 25.00 | Salofalk [FD] |

**mesalazine 1 g modified release tablet, 60**

| 3413P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *134.14 | 25.00 | Pentasa [FP] |

**mesalazine 1 g enteric tablet, 60**

| 11554D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *134.78 | 25.00 | Salofalk [FD] |

**mesalazine 1 g modified release granules, 100 sachets**

| 12203G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 105.07 | 25.00 | Pentasa [FP] |

**mesalazine 2 g modified release granules, 60 sachets**

| 2287J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 126.66 | 25.00 | Pentasa [FP] |

## MESALAZINE

**Restricted benefit**

***16491***

Ulcerative colitis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

***16603***

Crohn disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**mesalazine 250 mg enteric tablet, 100**

| 13423L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *75.76 | 25.00 | Mesasal [GO] |

**mesalazine 500 mg enteric tablet, 100**

| 13362G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *231.80 | 25.00 | Salofalk [FD] |

**mesalazine 500 mg modified release tablet, 100**

| 13396C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *231.80 | 25.00 | Pentasa [FP] |

**mesalazine 1 g modified release granules, 100 sachets**

| 13355X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *199.86 | 25.00 | Pentasa [FP] |

**mesalazine 1 g enteric tablet, 60**

| 13394Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *260.20 | 25.00 | Salofalk [FD] |

**mesalazine 1 g modified release tablet, 60**

| 13576M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *258.92 | 25.00 | Pentasa [FP] |

**mesalazine 2 g modified release granules, 60 sachets**

| 13397D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *243.96 | 25.00 | Pentasa [FP] |

## MESALAZINE

**Note** Not for the treatment of Crohn disease

**Note** Pharmaceutical benefits that have form pack size mesalazine 1.2 g modified release tablet, 60 and mesalazine 1.2 g modified release tablet, 120 are equivalent for the purposes of substitution.

**Restricted benefit**

***16552***

Ulcerative colitis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**mesalazine 1.2 g modified release tablet, 60**

| 9353G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *169.52 | 25.00 | [a] Mesalazine 1.2 TAKEDA [NQ]<br>[a] MEZTAS [TN] | [a] Mezavant [TK] |

**mesalazine 1.2 g modified release tablet, 120**

| 13247F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 169.54 | 25.00 | [a] MESALZ [RA] |

## MESALAZINE

**Note** Not for the treatment of Crohn disease

**Note** Pharmaceutical benefits that have form pack size mesalazine 1.2 g modified release tablet, 60 and mesalazine 1.2 g modified release tablet, 120 are equivalent for the purposes of substitution.

**Restricted benefit**

***16491***

Ulcerative colitis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**mesalazine 1.2 g modified release tablet, 120**

| 13356Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *329.72 | 25.00 | [a] MESALZ [RA] |

**mesalazine 1.2 g modified release tablet, 60**

| 13487W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *329.68 | 25.00 | [a] Mesalazine 1.2 TAKEDA [NQ]<br>[a] MEZTAS [TN] | [a] Mezavant [TK] |

## MESALAZINE

**Note** Not for the treatment of Crohn disease

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***16633***

Mild to moderate ulcerative proctitis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**mesalazine 1 g suppository, 30**

| 5461K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 98.14 | 25.00 | Salofalk [FD] |

**mesalazine 1 g suppository, 28**

| 12198B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.95 | 25.00 | Pentasa [FP] |

## MESALAZINE

**Note** Not for the treatment of Crohn disease

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16632***

Mild to moderate ulcerative colitis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**mesalazine 1 g/application foam, 14 applications**

| 8768L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *241.52 | 25.00 | Salofalk [FD] |

**mesalazine 1 g/100 mL enema, 7 x 100 mL**

| 8753Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *210.00 | 25.00 | Pentasa [FP] |

**mesalazine 2 g/60 mL enema, 7 x 60 mL**

| 8616L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *210.00 | 25.00 | Salofalk [FD] |

**mesalazine 4 g/60 mL enema, 7 x 60 mL**

| 8617M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *323.20 | 25.00 | Salofalk [FD] |

## MESALAZINE

**Note** Not for the treatment of Crohn disease

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16656***

Mild to moderate ulcerative colitis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**mesalazine 1 g/application foam, 14 applications**

| 14840C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *473.72 | 25.00 | Salofalk [FD] |

**mesalazine 1 g/100 mL enema, 7 x 100 mL**

| 14848L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *410.60 | 25.00 | Pentasa [FP] |

**mesalazine 2 g/60 mL enema, 7 x 60 mL**

| 14838Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *410.60 | 25.00 | Salofalk [FD] |

**mesalazine 4 g/60 mL enema, 7 x 60 mL**

| 14847K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *637.00 | 25.00 | Salofalk [FD] |

## MESALAZINE

**Note** Not for the treatment of Crohn disease

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***16548***

Mild to moderate ulcerative proctitis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**mesalazine 1 g suppository, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14843F NP | 2 | 5 | 0.00 | *185.30 | 25.00 | Salofalk [FD] |

**mesalazine 1 g suppository, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14850N NP | 2 | 5 | 0.00 | *151.30 | 25.00 | Pentasa [FP] |

## OLSALAZINE

**Note** Not for the treatment of Crohn disease

**Authority Required (STREAMLINED)**

***16658***

Ulcerative colitis

**Clinical criteria:**

- Patient must have had a documented hypersensitivity reaction to a sulphonamide; **OR**
- Patient must be intolerant to sulfasalazine.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**olsalazine sodium 250 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1728Y NP | 1 | 5 | 0.00 | 45.00 | 25.00 | Dipentum [IX] |

**olsalazine sodium 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8086N NP | 1 | 5 | 0.00 | 68.34 | 25.00 | Dipentum [IX] |

## SULFASALAZINE

**Restricted benefit**

***16524***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**sulfasalazine 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2093E NP | 2 | 5 | 0.00 | *52.54 | 25.00 | Salazopyrin [PF] |

**sulfasalazine 500 mg enteric tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2096H NP | 2 | 5 | 0.00 | *56.40 | 25.00 | [a] Pyralin EN [FZ] | |
| | | | [B]3.88 | *60.28 | 25.00 | [a] Salazopyrin-EN [PF] | |

## SULFASALAZINE

**Restricted benefit**

***16493***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**sulfasalazine 500 mg enteric tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13433B NP | 4 | 5 | 0.00 | *98.44 | 25.00 | [a] Pyralin EN [FZ] | |
| | | | [B]7.76 | *106.20 | 25.00 | [a] Salazopyrin-EN [PF] | |

**sulfasalazine 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13557M NP | 4 | 5 | 0.00 | *90.72 | 25.00 | Salazopyrin [PF] |

# DIGESTIVES, INCL. ENZYMES

## DIGESTIVES, INCL. ENZYMES

### *Enzyme preparations*

### PANCREATIC EXTRACT

**Restricted benefit**

***16559***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**pancreatic extract 10 000 units modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8020D NP | 5 | 10 | 0.00 | *142.69 | 25.00 | Creon 10,000 [GO] |

**pancreatic extract 25 000 units modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8021E NP | 2 | 10 | 0.00 | *115.66 | 25.00 | Creon 25,000 [GO] |

**pancreatic extract 35 000 units modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12595X NP | 2 | 10 | 0.00 | *158.14 | 25.00 | Creon 35,000 [GO] |

**pancreatic extract 5000 units/100 mg enteric coated granules, 20 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5453B NP | 3 | 10 | 0.00 | *111.33 | 25.00 | Creon Micro [GO] |

### PANCREATIC EXTRACT

**Restricted benefit**

***16508***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**pancreatic extract 35 000 units modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13407P NP | 4 | 10 | 0.00 | *306.92 | 25.00 | Creon 35,000 [GO] |

**pancreatic extract 25 000 units modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13470Y NP | 4 | 10 | 0.00 | *221.96 | 25.00 | Creon 25,000 [GO] |

**pancreatic extract 10 000 units modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13560Q NP | 10 | 10 | 0.00 | *276.04 | 25.00 | Creon 10,000 [GO] |

**pancreatic extract 5000 units/100 mg enteric coated granules, 20 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13375Y NP | 6 | 10 | 0.00 | *213.00 | 25.00 | Creon Micro [GO] |

# DRUGS USED IN DIABETES

## INSULINS AND ANALOGUES

### *Insulins and analogues for injection, fast-acting*

### INSULIN ASPART

**insulin aspart 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8435Y NP | 5 | 1 | 0.00 | *163.64 | 25.00 | NovoRapid Penfill 3 mL [NO] |

**insulin aspart 100 units/mL injection, 5 x 3 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12254Y NP | 5 | 1 | 0.00 | *163.64 | 25.00 | NovoRapid FlexPen [NF] |

**insulin aspart 100 units/mL fast acting injection, 5 x 3 mL cartridges**

| 13651L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 1 | 0.00 | *163.64 | 25.00 | Fiasp Penfill [NO] |

**insulin aspart 100 units/mL injection, 1 x 10 mL vial**

| 8571D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 2 | 0.00 | *99.49 | 25.00 | NovoRapid [NO] |

## INSULIN GLULISINE

**insulin glulisine 100 units/mL injection, 5 x 3 mL cartridges**

| 1921D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 1 | 0.00 | *163.69 | 25.00 | Apidra [AV] |

**insulin glulisine 100 units/mL injection, 5 x 3 mL pen devices**

| 12268Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 1 | 0.00 | *163.69 | 25.00 | Apidra SoloStar [SW] |

## INSULIN LISPRO

**insulin lispro 100 units/mL injection, 5 x 3 mL cartridges**

| 8212F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 1 | 0.00 | *163.64 | 25.00 | Humalog [LY] |

**insulin lispro 200 units/mL injection, 5 x 3 mL pen devices**

| 11645X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 1 | 0.00 | *260.04 | 25.00 | Humalog U200 Kwikpen [LY] |

**insulin lispro 100 units/mL injection, 5 x 3 mL pen devices**

| 12237C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 1 | 0.00 | *163.64 | 25.00 | Humalog KwikPen [KP] |

## INSULIN NEUTRAL HUMAN

**insulin neutral human 100 units/mL injection, 5 x 3 mL cartridges**

| 1762R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 5 | 1 | 0.00 | *137.99 | 25.00 | Actrapid Penfill 3 mL [NO] | Humulin R [LY] |

**insulin neutral human 100 units/mL injection, 1 x 10 mL vial**

| 1531N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 2 | 0.00 | *85.24 | 25.00 | Actrapid [NO] |

### *Insulins and analogues for injection, intermediate-acting*

## INSULIN ISOPHANE HUMAN

**insulin isophane human 100 units/mL injection, 5 x 3 mL cartridges**

| 1761Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 5 | 1 | 0.00 | *137.99 | 25.00 | Humulin NPH [LY] | Protaphane Penfill 3 mL [NO] |

**insulin isophane human 100 units/mL injection, 1 x 10 mL vial**

| 1533Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 2 | 0.00 | *85.24 | 25.00 | Protaphane [NO] |

### *Insulins and analogues for injection, intermediate- or long-acting combined with fast-acting*

## INSULIN ASPART + INSULIN ASPART PROTAMINE

**insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL cartridges**

| 8609D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 1 | 0.00 | *163.64 | 25.00 | NovoMix 30 Penfill 3 mL [NO] |

**insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL pen devices**

| 12238D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 1 | 0.00 | *163.64 | 25.00 | NovoMix 30 FlexPen [NF] |

## INSULIN DEGLUDEC + INSULIN ASPART

**Note** Special Pricing Arrangements apply.

**insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11426J | | | | | | |
| NP | 5 | 1 | 0.00 | *370.79 | 25.00 | Ryzodeg Penfill [NO] |

### INSULIN LISPRO + INSULIN LISPRO PROTAMINE

**insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8390N | | | | | | |
| NP | 5 | 1 | 0.00 | *163.64 | 25.00 | Humalog Mix25 [LY] |

**insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8874C | | | | | | |
| NP | 5 | 1 | 0.00 | *163.64 | 25.00 | Humalog Mix50 [LY] |

**insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12234X | | | | | | |
| NP | 5 | 1 | 0.00 | *163.64 | 25.00 | Humalog Mix25 KwikPen [KP] |

**insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12261H | | | | | | |
| NP | 5 | 1 | 0.00 | *163.64 | 25.00 | Humalog Mix50 KwikPen [KP] |

### INSULIN NEUTRAL HUMAN + INSULIN ISOPHANE HUMAN

**insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1763T | | | | | | |
| NP | 5 | 1 | 0.00 | *137.99 | 25.00 | Humulin 30/70 [LY] |

## *Insulins and analogues for injection, long-acting*

### INSULIN DEGLUDEC

**Note** Special Pricing Arrangements apply.

**Restricted benefit**
***5174***
Type 1 diabetes

**insulin degludec 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15393E | | | | | | |
| NP | 5 | 1 | 0.00 | *370.79 | 25.00 | Tresiba Penfill [NO] |

### INSULIN DETEMIR

**Note** Special Pricing Arrangements apply.

**Restricted benefit**
***5174***
Type 1 diabetes

**insulin detemir 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9040T | | | | | | |
| NP | 5 | 1 | 0.00 | *346.74 | 25.00 | Levemir Penfill [NO] |

**insulin detemir 100 units/mL injection, 5 x 3 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12236B | | | | | | |
| NP | 5 | 1 | 0.00 | *346.74 | 25.00 | Levemir FlexPen [NF] |

### INSULIN GLARGINE

**insulin glargine 100 units/mL injection, 5 x 3 mL cartridges**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9039R | | | | | | |
| NP | 5 | 1 | 0.00 | *182.99 | 25.00 | Optisulin [GZ] |

**insulin glargine 100 units/mL injection, 5 x 3 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11815W | | | | | | |
| NP | 5 | 1 | 0.00 | *182.99 | 25.00 | Optisulin SoloStar [WA] |

### INSULIN GLARGINE

**Note** Special Pricing Arrangements apply.

**insulin glargine 300 units/mL injection, 3 x 1.5 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11308E NP | 5 | 1 | 0.00 | *249.44 | 25.00 | Toujeo Solostar [SW] |

**insulin glargine 300 units/mL injection, 5 x 1.5 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11302W NP | 5 | 1 | 0.00 | *409.39 | 25.00 | Toujeo Solostar [SW] |

## BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

### *Biguanides*

### METFORMIN

**Restricted benefit**

***16261***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

**metformin hydrochloride 500 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2430X NP MW | 1 | 5 | 0.00 | 17.60 | 19.14 | [a] APX-METFORMIN [TY] | [a] Blooms The Chemist Metformin 500 mg [BG] |
| | | | | | | [a] Diaformin [AF] | [a] Diaformin Viatris [MQ] |
| | | | | | | [a] FORMET 500 [RF] | [a] Glucobete 500 [ZS] |
| | | | | | | [a] Metformin GH [HQ] | [a] Metformin Sandoz [SZ] |
| | | | | | | [a] METFORMIN-WGR [WG] | |
| | | | [B]5.20 | 22.80 | 19.14 | [a] Diabex [AL] | |

**metformin hydrochloride 500 mg modified release tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9435N NP MW | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Metformin XR 500 [TX] | [a] Blooms Metformin XR [BG] |
| | | | | | | [a] Diaformin Alphapharm XR [MQ] | [a] Metex XR [RW] |
| | | | | | | [a] Metformin Lupin XR [GQ] | [a] Metformin Sandoz XR [SZ] |
| | | | | | | [a] METFORMIN-WGR XR [WG] | [a] Pharmacor Metformin XR [CR] |
| | | | [B]5.12 | 23.72 | 20.14 | [a] Diabex XR 500 [AL] | |

**metformin hydrochloride 850 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1801T NP MW | 1 | 5 | 0.00 | 17.60 | 19.14 | [a] APX-METFORMIN [TY] | [a] Blooms The Chemist Metformin 850 mg [BG] |
| | | | | | | [a] Diaformin 850 [AF] | [a] Diaformin Viatris [MQ] |
| | | | | | | [a] FORMET 850 [RF] | [a] Glucobete 850 [ZS] |
| | | | | | | [a] Metformin Sandoz [SZ] | [a] METFORMIN-WGR [WG] |
| | | | [B]5.20 | 22.80 | 19.14 | [a] Diabex 850 [AL] | |

**metformin hydrochloride 1 g modified release tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3439B NP MW | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Metformin XR 1000 [TX] | [a] Blooms Metformin XR [BG] |
| | | | | | | [a] Diaformin Alphapharm XR [MQ] | [a] Diaformin Viatris XR [VY] |
| | | | | | | [a] Diaformin XR 1000 [AF] | [a] METEX XR [RF] |
| | | | | | | [a] Metformin Lupin XR [GQ] | [a] Metformin Sandoz XR [SZ] |
| | | | | | | [a] METFORMIN-WGR XR [WG] | [a] Pharmacor Metformin XR [CR] |
| | | | [B]5.12 | 23.72 | 20.14 | [a] Diabex XR 1000 [AL] | |

**metformin hydrochloride 1 g tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8607B NP MW | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APX-METFORMIN [TY] | [a] Blooms The Chemist Metformin 1000 mg [BG] |

| 8607B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Diaformin 1000 [AF] | [a] Diaformin Viatris [MQ] |
| | | | | | | [a] Formet 1000 [RW] | [a] Glucobete 1000 [ZS] |
| | | | | | | [a] Metformin GH [HQ] | [a] Metformin Sandoz [SZ] |
| | | | | | | [a] METFORMIN-WGR [WG] | |
| | | | [B]4.68 | 23.28 | 20.14 | [a] Diabex 1000 [AL] | |

## METFORMIN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### metformin hydrochloride 500 mg modified release tablet, 120

| 13899M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Metformin XR 500 [TX] | [a] Blooms Metformin XR [BG] |
| | | | | | | [a] Diaformin Alphapharm XR [MQ] | [a] Metex XR [RW] |
| | | | | | | [a] Metformin Lupin XR [GQ] | [a] Metformin Sandoz XR [SZ] |
| | | | | | | [a] METFORMIN-WGR XR [WG] | [a] Pharmacor Metformin XR [CR] |
| | | | [B]10.24 | 33.08 | 24.38 | [a] Diabex XR 500 [AL] | |

### metformin hydrochloride 500 mg tablet, 100

| 13976N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *20.84 | 22.38 | [a] APX-METFORMIN [TY] | [a] Blooms The Chemist Metformin 500 mg [BG] |
| | | | | | | [a] Diaformin [AF] | [a] Diaformin Viatris [MQ] |
| | | | | | | [a] FORMET 500 [RF] | [a] Glucobete 500 [ZS] |
| | | | | | | [a] Metformin GH [HQ] | [a] Metformin Sandoz [SZ] |
| | | | | | | [a] METFORMIN-WGR [WG] | |
| | | | [B]10.40 | 31.24 | 22.38 | [a] Diabex [AL] | |

### metformin hydrochloride 850 mg tablet, 60

| 13952H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *20.84 | 22.38 | [a] APX-METFORMIN [TY] | [a] Blooms The Chemist Metformin 850 mg [BG] |
| | | | | | | [a] Diaformin 850 [AF] | [a] Diaformin Viatris [MQ] |
| | | | | | | [a] FORMET 850 [RF] | [a] Glucobete 850 [ZS] |
| | | | | | | [a] Metformin Sandoz [SZ] | [a] METFORMIN-WGR [WG] |
| | | | [B]10.40 | 31.24 | 22.38 | [a] Diabex 850 [AL] | |

### metformin hydrochloride 1 g modified release tablet, 60

| 13847T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Metformin XR 1000 [TX] | [a] Blooms Metformin XR [BG] |
| | | | | | | [a] Diaformin Alphapharm XR [MQ] | [a] Diaformin Viatris XR [VY] |
| | | | | | | [a] Diaformin XR 1000 [AF] | [a] METEX XR [RF] |
| | | | | | | [a] Metformin Lupin XR [GQ] | [a] Metformin Sandoz XR [SZ] |
| | | | | | | [a] METFORMIN-WGR XR [WG] | [a] Pharmacor Metformin XR [CR] |
| | | | [B]10.24 | 33.08 | 24.38 | [a] Diabex XR 1000 [AL] | |

### metformin hydrochloride 1 g tablet, 90

| 14056T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APX-METFORMIN [TY] | [a] Blooms The Chemist Metformin 1000 mg [BG] |
| | | | | | | [a] Diaformin 1000 [AF] | [a] Diaformin Viatris [MQ] |
| | | | | | | [a] Formet 1000 [RW] | [a] Glucobete 1000 [ZS] |
| | | | | | | [a] Metformin GH [HQ] | [a] Metformin Sandoz [SZ] |
| | | | | | | [a] METFORMIN-WGR [WG] | |
| | | | [B]9.36 | 32.20 | 24.38 | [a] Diabex 1000 [AL] | |

## *Sulfonylureas*

## GLIBENCLAMIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

### glibenclamide 5 mg tablet, 100

| 2939Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | Daonil [SW] |

## GLIBENCLAMIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### glibenclamide 5 mg tablet, 100

| 13868X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | Daonil [SW] |

## GLICLAZIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

### gliclazide 30 mg modified release tablet, 100

| 8535F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.51 | 21.05 | [a] APO-Gliclazide MR [TX] | [a] Gliclazide MR Viatris [AL] |
| | | | | | | [a] Gliclazide Sandoz MR [SZ] | [a] Pharmacor Gliclazide MR [CR] |

### gliclazide 60 mg modified release tablet, 60

| 9302N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.52 | 20.06 | [a] ARDIX GLICLAZIDE 60mg MR [XT] | [a] ARX-Gliclazide MR [XW] |
| | | | | | | [a] Gliclazide Lupin MR [GQ] | [a] Gliclazide Sandoz MR [SZ] |
| | | | | | | [a] Pharmacor Gliclazide MR [CR] | |
| | | | [B]9.58 | 28.10 | 20.06 | [a] Diamicron 60mg MR [SE] | |

### gliclazide 80 mg tablet, 100

| 2449X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.37 | 20.91 | [a] APX-Gliclazide [TY] | [a] Nidem [RW] |

## GLICLAZIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### gliclazide 30 mg modified release tablet, 100

| 14740T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.66 | 25.00 | [a] APO-Gliclazide MR [TX] | [a] Gliclazide MR Viatris [AL] |
| | | | | | | [a] Gliclazide Sandoz MR [SZ] | [a] Pharmacor Gliclazide MR [CR] |

### gliclazide 60 mg modified release tablet, 60

| 13922R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.68 | 24.22 | [a] ARDIX GLICLAZIDE 60mg MR [XT] | [a] ARX-Gliclazide MR [XW] |
| | | | | | | [a] Gliclazide Lupin MR [GQ] | [a] Gliclazide Sandoz MR [SZ] |
| | | | | | | [a] Pharmacor Gliclazide MR [CR] | |
| | | | [B]19.16 | 41.84 | 24.22 | [a] Diamicron 60mg MR [SE] | |

### gliclazide 80 mg tablet, 100

| 13896J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.38 | 25.00 | [a] APX-Gliclazide [TY] | [a] Nidem [RW] |

## GLIMEPIRIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

### glimepiride 1 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8450R | | | | | | | |
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] ARX-GLIMEPIRIDE [XT] | [a] Glimepiride Sandoz [SZ] |
| | | | | | | [a] GLIMEPIRIDE-WGR [WG] | |

### glimepiride 2 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8451T | | | | | | | |
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] ARX-GLIMEPIRIDE [XT] | [a] Glimepiride Sandoz [SZ] |
| | | | | | | [a] GLIMEPIRIDE-WGR [WG] | |

### glimepiride 3 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8533D | | | | | | | |
| NP | 1 | 5 | 0.00 | 17.29 | 18.83 | [a] ARX-GLIMEPIRIDE [XT] | [a] Glimepiride Sandoz [SZ] |

### glimepiride 4 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8452W | | | | | | | |
| NP | 1 | 5 | 0.00 | 17.80 | 19.34 | [a] ARX-GLIMEPIRIDE [XT] | [a] Glimepiride Sandoz [SZ] |
| | | | | | | [a] GLIMEPIRIDE-WGR [WG] | |

## GLIMEPIRIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### glimepiride 1 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13848W | | | | | | | |
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] ARX-GLIMEPIRIDE [XT] | [a] Glimepiride Sandoz [SZ] |
| | | | | | | [a] GLIMEPIRIDE-WGR [WG] | |

### glimepiride 2 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13870B | | | | | | | |
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] ARX-GLIMEPIRIDE [XT] | [a] Glimepiride Sandoz [SZ] |
| | | | | | | [a] GLIMEPIRIDE-WGR [WG] | |

### glimepiride 3 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14020X | | | | | | | |
| NP | 2 | 5 | 0.00 | *20.22 | 21.76 | [a] ARX-GLIMEPIRIDE [XT] | [a] Glimepiride Sandoz [SZ] |

### glimepiride 4 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14055R | | | | | | | |
| NP | 2 | 5 | 0.00 | *21.24 | 22.78 | [a] ARX-GLIMEPIRIDE [XT] | [a] Glimepiride Sandoz [SZ] |
| | | | | | | [a] GLIMEPIRIDE-WGR [WG] | |

## GLIPIZIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

### glipizide 5 mg tablet, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2440K | | | | | | | |
| NP | 1 | 5 | 0.00 | 20.85 | 22.39 | [a] Melizide [AF] | [a] Minidiab [PF] |

## GLIPIZIDE

**Caution** Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### glipizide 5 mg tablet, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14019W | | | | | | | |
| NP | 2 | 5 | 0.00 | *27.34 | 25.00 | [a] Melizide [AF] | [a] Minidiab [PF] |

## *Combinations of oral blood glucose lowering drugs*

## ALOGLIPTIN + METFORMIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15276***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

### alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56

| 10033C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 53.09 | 25.00 | Nesina Met 12.5/500 [TK] |

### alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56

| 10032B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 54.03 | 25.00 | Nesina Met 12.5/850 [TK] |

### alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56

| 10035E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 54.40 | 25.00 | Nesina Met 12.5/1000 [TK] |

## ALOGLIPTIN + METFORMIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15288***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

### alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56

| 14062D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *91.82 | 25.00 | Nesina Met 12.5/500 [TK] |

**alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56**

| 14061C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *93.70 | 25.00 | Nesina Met 12.5/850 [TK] |

**alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56**

| 13989G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *94.44 | 25.00 | Nesina Met 12.5/1000 [TK] |

## DAPAGLIFLOZIN + METFORMIN

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***16158***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have cardiovascular disease; **OR**
- Patient must be at high risk of a cardiovascular event; **OR**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au.

High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

**Authority Required (STREAMLINED)**

***15289***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56**

| 10510E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 54.32 | 25.00 | Xigduo XR 5/1000 [AP] |

**dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28**

| 10516L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 52.29 | 25.00 | Xigduo XR 10/500 [AP] |

**dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28**

| 10515K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 53.06 | 25.00 | Xigduo XR 10/1000 [AP] |

## DAPAGLIFLOZIN + METFORMIN

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***16162***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have cardiovascular disease; **OR**
- Patient must be at high risk of a cardiovascular event; **OR**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au.

High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

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**Authority Required (STREAMLINED)**

***15267***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

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### dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56

| 13851B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *94.28 | 25.00 | Xigduo XR 5/1000 [AP] |

### dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28

| 14028H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *90.22 | 25.00 | Xigduo XR 10/500 [AP] |

### dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28

| 13875G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *91.76 | 25.00 | Xigduo XR 10/1000 [AP] |

## DAPAGLIFLOZIN + SITAGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***15269***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with at least metformin, **AND**

- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

**Dapagliflozin 10 mg + sitagliptin 100 mg tablet, 28**

| 14638K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 66.10 | 25.00 | Sidapvia 10/100 [AP] |

## DAPAGLIFLOZIN + SITAGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15270***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

**Dapagliflozin 10 mg + sitagliptin 100 mg tablet, 28**

| 14645T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *118.02 | 25.00 | Sidapvia 10/100 [AP] |

## EMPAGLIFLOZIN + LINAGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15269***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

**empagliflozin 10 mg + linagliptin 5 mg tablet, 30**

| 11269D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 76.64 | 25.00 | Glyxambi [BY] |

**empagliflozin 25 mg + linagliptin 5 mg tablet, 30**

| 11303X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 76.64 | 25.00 | Glyxambi [BY] |

## EMPAGLIFLOZIN + LINAGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15270***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

**empagliflozin 10 mg + linagliptin 5 mg tablet, 30**

| 13904T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *140.14 | 25.00 | Glyxambi [BY] |

**empagliflozin 25 mg + linagliptin 5 mg tablet, 30**

| 13958P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *140.14 | 25.00 | Glyxambi [BY] |

## EMPAGLIFLOZIN + METFORMIN

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***16158***

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have cardiovascular disease; **OR**
- Patient must be at high risk of a cardiovascular event; **OR**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au.

High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

**Authority Required (STREAMLINED)**

***15289***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60**

| 10626G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 55.56 | 25.00 | Jardiamet 5 mg/500 mg [BY] |

**empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60**

| 10627H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 56.95 | 25.00 | Jardiamet 5 mg/1000 mg [BY] |

**empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60**

| 10633P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 55.56 | 25.00 | Jardiamet 12.5 mg/500 mg [BY] |

**empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60**

| 10677Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 56.95 | 25.00 | Jardiamet 12.5 mg/1000 mg [BY] |

## EMPAGLIFLOZIN + METFORMIN

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***16162***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have cardiovascular disease; **OR**
- Patient must be at high risk of a cardiovascular event; **OR**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au.

High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

**Authority Required (STREAMLINED)**

***15267***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14029J NP | 2 | 5 | 0.00 | *96.76 | 25.00 | Jardiamet 5 mg/500 mg [BY] |

**empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13852C NP | 2 | 5 | 0.00 | *99.54 | 25.00 | Jardiamet 5 mg/1000 mg [BY] |

**empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13903R NP | 2 | 5 | 0.00 | *96.76 | 25.00 | Jardiamet 12.5 mg/500 mg [BY] |

**empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13987E NP | 2 | 5 | 0.00 | *99.54 | 25.00 | Jardiamet 12.5 mg/1000 mg [BY] |

## LINAGLIPTIN + METFORMIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15276***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10038H NP | 1 | 5 | 0.00 | 56.32 | 25.00 | Trajentamet [BY] |

**linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10045Q NP | 1 | 5 | 0.00 | 57.13 | 25.00 | Trajentamet [BY] |

**linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10044P NP | 1 | 5 | 0.00 | 57.59 | 25.00 | Trajentamet [BY] |

## LINAGLIPTIN + METFORMIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15288***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

### linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60

| 13959Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *98.28 | 25.00 | Trajentamet [BY] |

### linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60

| 14065G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *99.90 | 25.00 | Trajentamet [BY] |

### linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60

| 13879L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *100.82 | 25.00 | Trajentamet [BY] |

## SAXAGLIPTIN + METFORMIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15276***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

### saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56

| 10048W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 54.42 | 25.00 | Kombiglyze XR 2.5/1000 [AP] |

**saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10055F NP | 1 | 5 | 0.00 | 52.47 | 25.00 | Kombiglyze XR 5/500 [AP] |

**saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10051B NP | 1 | 5 | 0.00 | 53.24 | 25.00 | Kombiglyze XR 5/1000 [AP] |

## SAXAGLIPTIN + METFORMIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15288***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13880M NP | 2 | 5 | 0.00 | *94.48 | 25.00 | Kombiglyze XR 2.5/1000 [AP] |

**saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14030K NP | 2 | 5 | 0.00 | *90.58 | 25.00 | Kombiglyze XR 5/500 [AP] |

**saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13876H NP | 2 | 5 | 0.00 | *92.12 | 25.00 | Kombiglyze XR 5/1000 [AP] |

## SITAGLIPTIN + METFORMIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15276***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56**

| 9449H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 35.56 | 25.00 | [a] Blooms The Chemist Sitagliptin/Metformin 50/500 [BG] | [a] Janumet [MK] |
| | | | | | | [a] SITAGLIPTIN/METFORMIN 50/500 SUN [RA] | [a] Sitagliptin/Metformin Mylan 50/500 [AF] |
| | | | | | | [a] Sitagliptin/Metformin Sandoz [SZ] | [a] SITAGLO-MET [CR] |
| | | | | | | [a] Velmetia [XT] | |

**sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56**

| 9450J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 36.27 | 25.00 | [a] Blooms The Chemist Sitagliptin/Metformin 50/850 [BG] | [a] Janumet [MK] |
| | | | | | | [a] SITAGLIPTIN/METFORMIN 50/850 SUN [RA] | [a] Sitagliptin/Metformin Mylan 50/850 [AF] |
| | | | | | | [a] Sitagliptin/Metformin Sandoz [SZ] | [a] SITAGLO-MET [CR] |
| | | | | | | [a] Velmetia [XT] | |

**sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56**

| 9451K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 36.59 | 25.00 | [a] Blooms The Chemist Sitagliptin/Metformin 50/1000 [BG] | [a] Janumet [MK] |
| | | | | | | [a] SITAGLIPTIN/METFORMIN 50/1000 SUN [RA] | [a] Sitagliptin/Metformin Mylan 50/1000 [AF] |
| | | | | | | [a] Sitagliptin/Metformin Sandoz [SZ] | [a] SITAGLO-MET [CR] |
| | | | | | | [a] Velmetia [XT] | |

**sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56**

| 10090C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 46.14 | 25.00 | [a] ARX-Sitagliptin/Metformin XR 50/1000 [XT] | [a] Janumet XR [MK] |
| | | | | | | [a] Sitagliptin/Metformin Sandoz XR [SZ] | [a] Sitagliptin/Metformin XR KND [CR] |
| | | | | | | [a] Sitagliptin/Metformin XR Mylan [AL] | |

**sitagliptin 100 mg + metformin hydrochloride 1 g modified release tablet, 28**

| 10089B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 45.11 | 25.00 | [a] ARX-Sitagliptin/Metformin XR 100/1000 [XT] | [a] Janumet XR [MK] |
| | | | | | | [a] Sitagliptin/Metformin Sandoz XR [SZ] | [a] Sitagliptin/Metformin XR KND [CR] |
| | | | | | | [a] Sitagliptin/Metformin XR Mylan [AL] | |

## SITAGLIPTIN + METFORMIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15288***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

### sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56

| 13994M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *56.76 | 25.00 | [a] Blooms The Chemist Sitagliptin/Metformin 50/500 [BG] | [a] Janumet [MK] |
| | | | | | | [a] SITAGLIPTIN/METFORMIN 50/500 SUN [RA] | [a] Sitagliptin/Metformin Mylan 50/500 [AF] |
| | | | | | | [a] Sitagliptin/Metformin Sandoz [SZ] | [a] SITAGLO-MET [CR] |
| | | | | | | [a] Velmetia [XT] | |

### sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56

| 14064F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *58.18 | 25.00 | [a] Blooms The Chemist Sitagliptin/Metformin 50/850 [BG] | [a] Janumet [MK] |
| | | | | | | [a] SITAGLIPTIN/METFORMIN 50/850 SUN [RA] | [a] Sitagliptin/Metformin Mylan 50/850 [AF] |
| | | | | | | [a] Sitagliptin/Metformin Sandoz [SZ] | [a] SITAGLO-MET [CR] |
| | | | | | | [a] Velmetia [XT] | |

### sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56

| 13990H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *77.92 | 25.00 | [a] ARX-Sitagliptin/Metformin XR 50/1000 [XT] | [a] Janumet XR [MK] |
| | | | | | | [a] Sitagliptin/Metformin Sandoz XR [SZ] | [a] Sitagliptin/Metformin XR KND [CR] |
| | | | | | | [a] Sitagliptin/Metformin XR Mylan [AL] | |

### sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56

| 14035Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *58.82 | 25.00 | [a] Blooms The Chemist Sitagliptin/Metformin 50/1000 [BG] | [a] Janumet [MK] |
| | | | | | | [a] SITAGLIPTIN/METFORMIN 50/1000 SUN [RA] | [a] Sitagliptin/Metformin Mylan 50/1000 [AF] |
| | | | | | | [a] Sitagliptin/Metformin Sandoz [SZ] | [a] SITAGLO-MET [CR] |
| | | | | | | [a] Velmetia [XT] | |

### sitagliptin 100 mg + metformin hydrochloride 1 g modified release tablet, 28

| 14031L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *75.86 | 25.00 | [a] ARX-Sitagliptin/Metformin XR 100/1000 [XT] | [a] Janumet XR [MK] |
| | | | | | | [a] Sitagliptin/Metformin Sandoz XR [SZ] | [a] Sitagliptin/Metformin XR KND [CR] |
| | | | | | | [a] Sitagliptin/Metformin XR Mylan [AL] | |

## VILDAGLIPTIN + METFORMIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15276***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60**

| 5474D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 41.04 | 25.00 | [a] ARX-Vildagliptin/Metformin 50/500 [XT] | [a] Galvumet 50/500 [NV] |

**vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60**

| 5475E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 41.64 | 25.00 | [a] ARX-Vildagliptin/Metformin 50/850 [XT] | [a] Galvumet 50/850 [NV] |

**vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60**

| 5476F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 41.97 | 25.00 | [a] ARX-Vildagliptin/Metformin 50/1000 [XT] | [a] Galvumet 50/1000 [NV] |

## VILDAGLIPTIN + METFORMIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15288***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately responsive to metformin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60**

| 13877J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *67.72 | 25.00 | [a] ARX-Vildagliptin/Metformin 50/500 [XT] | [a] Galvumet 50/500 [NV] |

**vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60**

| 13991J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *68.92 | 25.00 | [a] ARX-Vildagliptin/Metformin 50/850 [XT] | [a] Galvumet 50/850 [NV] |

**vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60**

| 14032M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *69.58 | 25.00 | [a] ARX-Vildagliptin/Metformin 50/1000 [XT] | [a] Galvumet 50/1000 [NV] |

## *Alpha glucosidase inhibitors*

### ACARBOSE

**acarbose 50 mg tablet, 90**

| 8188Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 28.42 | 25.00 | [a] Acarbose Viatris [AL] | [a] GLYBOSAY [RW] |

### ACARBOSE

**Note** Pharmaceutical benefits that have the form acarbose 100 mg tablet can be substituted for Acarbose 100 mg tablets (Morningside Healthcare, UK) in the case of a shortage.

**acarbose 100 mg tablet, 90**

| 8189B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 34.27 | 25.00 | [a] Acarbose Viatris [AL] | [a] GLYBOSAY [RW] |

**acarbose 100 mg tablet, 90**

| 14722W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 117.24 | 25.00 | [a] Acarbose 100 mg tablets (Morningside Healthcare, UK) [LM] |

### ACARBOSE

**Note** Pharmaceutical benefits that have the form acarbose 50 mg tablet can be substituted for Acarbose 50 mg tablets (Morningside Healthcare, UK) in the case of a shortage.

**acarbose 50 mg tablet, 90**

| 14735M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 95.92 | 25.00 | [a] Acarbose 50 mg tablets (Morningside Healthcare, UK) [LM] |

### ACARBOSE

**Note** Pharmaceutical benefits that have the form acarbose 100 mg tablet can be substituted for Acarbose 100 mg tablets (Morningside Healthcare, UK) in the case of a shortage.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**acarbose 100 mg tablet, 90**

| 13869Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *54.18 | 25.00 | [a] Acarbose Viatris [AL] | [a] GLYBOSAY [RW] |

**acarbose 100 mg tablet, 90**

| 14734L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *225.12 | 25.00 | [a] Acarbose 100 mg tablets (Morningside Healthcare, UK) [LM] |

### ACARBOSE

**Note** Pharmaceutical benefits that have the form acarbose 50 mg tablet can be substituted for Acarbose 50 mg tablets (Morningside Healthcare, UK) in the case of a shortage.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**acarbose 50 mg tablet, 90**

| 13955L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *42.48 | 25.00 | [a] Acarbose Viatris [AL] | [a] GLYBOSAY [RW] |

**acarbose 50 mg tablet, 90**

| 14726C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *180.64 | 25.00 | [a] Acarbose 50 mg tablets (Morningside Healthcare, UK) [LM] |

***Thiazolidinediones***

## PIOGLITAZONE

**Restricted benefit**

***15321***

Diabetes mellitus type 2

**pioglitazone 15 mg tablet, 28**

| 8694N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.81 | 22.35 | [a] ARX-PIOGLITAZONE [XT] | [a] Vexazone [AF] |

**Pioglitazone 15 mg tablet, 30**

| 15261F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 21.26 | 22.80 | Actos [GQ] |

**pioglitazone 30 mg tablet, 28**

| 8695P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 24.28 | 25.00 | [a] ARX-PIOGLITAZONE [XT] | [a] Vexazone [AF] |

**Pioglitazone 30 mg tablet, 30**

| 15223F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 24.99 | 25.00 | Actos [GQ] |

**pioglitazone 45 mg tablet, 28**

| 8696Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 27.26 | 25.00 | [a] ARX-PIOGLITAZONE [XT] | [a] Vexazone [AF] |

**Pioglitazone 45 mg tablet, 30**

| 15222E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 28.18 | 25.00 | Actos [GQ] |

## PIOGLITAZONE

**Restricted benefit**

***15290***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pioglitazone 15 mg tablet, 28**

| 13898L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *27.26 | 25.00 | [a] ARX-PIOGLITAZONE [XT] | [a] Vexazone [AF] |

**Pioglitazone 15 mg tablet, 30**

| 15236X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *28.16 | 25.00 | Actos [GQ] |

**pioglitazone 30 mg tablet, 28**

| 13921Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *34.20 | 25.00 | [a] ARX-PIOGLITAZONE [XT] | [a] Vexazone [AF] |

**Pioglitazone 30 mg tablet, 30**

| 15267M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *35.62 | 25.00 | Actos [GQ] |

**pioglitazone 45 mg tablet, 28**

| 14057W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *40.16 | 25.00 | [a] ARX-PIOGLITAZONE [XT] | [a] Vexazone [AF] |

**Pioglitazone 45 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15229M NP | 2 | 5 | 0.00 | *42.00 | 25.00 | Actos [GQ] |

## *Dipeptidyl peptidase 4 (DPP-4) inhibitors*

### ALOGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15261***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**alogliptin 6.25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2944Y NP | 1 | 5 | 0.00 | 51.70 | 25.00 | Nesina [TK] |

**alogliptin 12.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2933J NP | 1 | 5 | 0.00 | 51.70 | 25.00 | Nesina [TK] |

**alogliptin 25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2986E NP | 1 | 5 | 0.00 | 51.70 | 25.00 | Nesina [TK] |

### ALOGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15287***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**alogliptin 6.25 mg tablet, 28**

| 13897K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *89.04 | 25.00 | Nesina [TK] |

**alogliptin 12.5 mg tablet, 28**

| 13977P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *89.04 | 25.00 | Nesina [TK] |

**alogliptin 25 mg tablet, 28**

| 13953J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *89.04 | 25.00 | Nesina [TK] |

## LINAGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15261***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**linagliptin 5 mg tablet, 30**

| 3387G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 54.37 | 25.00 | Trajenta [BY] |

## LINAGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15287***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**linagliptin 5 mg tablet, 30**

| 13954K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *94.38 | 25.00 | Trajenta [BY] |

## SAXAGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15261***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**saxagliptin 2.5 mg tablet, 28**

| 10128C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 51.70 | 25.00 | Onglyza [AP] |

**saxagliptin 5 mg tablet, 28**

| 8983T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 51.70 | 25.00 | Onglyza [AP] |

## SAXAGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15287***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**saxagliptin 2.5 mg tablet, 28**

| 13895H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *89.04 | 25.00 | Onglyza [AP] |

**saxagliptin 5 mg tablet, 28**

| 13923T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *89.04 | 25.00 | Onglyza [AP] |

## SITAGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15261***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**sitagliptin 25 mg tablet, 28**

| 9180E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 31.55 | 25.00 | [a] Januvia [MK] | [a] Sitagliptin Lupin [GQ] |
| | | | | | | [a] Sitagliptin Mylan [AF] | [a] Sitagliptin Sandoz Pharma [SZ] |
| | | | | | | [a] Sitagliptin SUN [RA] | [a] Sitaglo [CR] |
| | | | | | | [a] Xelevia [XT] | |

**sitagliptin 50 mg tablet, 28**

| 9181F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 31.55 | 25.00 | [a] Januvia [MK] | [a] Sitagliptin Lupin [GQ] |
| | | | | | | [a] Sitagliptin Mylan [AF] | [a] Sitagliptin Sandoz Pharma [SZ] |
| | | | | | | [a] Sitagliptin SUN [RA] | [a] Sitaglo [CR] |
| | | | | | | [a] Xelevia [XT] | |

**sitagliptin 100 mg tablet, 28**

| 9182G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 31.55 | 25.00 | [a] Januvia [MK] | [a] Sitagliptin Lupin [GQ] |
| | | | | | | [a] Sitagliptin Mylan [AF] | [a] Sitagliptin Sandoz Pharma [SZ] |
| | | | | | | [a] Sitagliptin SUN [RA] | [a] Sitaglo [CR] |
| | | | | | | [a] Xelevia [XT] | |

## SITAGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15287***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

### sitagliptin 25 mg tablet, 28

| 14021Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *48.74 | 25.00 | [a] Januvia [MK] | [a] Sitagliptin Lupin [GQ] |
| | | | | | | [a] Sitagliptin Mylan [AF] | [a] Sitagliptin Sandoz Pharma [SZ] |
| | | | | | | [a] Sitagliptin SUN [RA] | [a] Sitaglo [CR] |
| | | | | | | [a] Xelevia [XT] | |

### sitagliptin 50 mg tablet, 28

| 14058X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *48.74 | 25.00 | [a] Januvia [MK] | [a] Sitagliptin Lupin [GQ] |
| | | | | | | [a] Sitagliptin Mylan [AF] | [a] Sitagliptin Sandoz Pharma [SZ] |
| | | | | | | [a] Sitagliptin SUN [RA] | [a] Sitaglo [CR] |
| | | | | | | [a] Xelevia [XT] | |

### sitagliptin 100 mg tablet, 28

| 13871C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *48.74 | 25.00 | [a] Januvia [MK] | [a] Sitagliptin Lupin [GQ] |
| | | | | | | [a] Sitagliptin Mylan [AF] | [a] Sitagliptin Sandoz Pharma [SZ] |
| | | | | | | [a] Sitagliptin SUN [RA] | [a] Sitaglo [CR] |
| | | | | | | [a] Xelevia [XT] | |

## VILDAGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15261***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**vildagliptin 50 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3415R NP | 1 | 5 | 0.00 | 40.98 | 25.00 | Galvus [NV] |

## VILDAGLIPTIN

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***15287***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

**vildagliptin 50 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13846R NP | 2 | 5 | 0.00 | *67.60 | 25.00 | Galvus [NV] |

### *Glucagon-like peptide-1 (GLP-1) analogues*

## DULAGLUTIDE

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15301***

Diabetes mellitus type 2

Treatment Phase: First PBS-prescription for this drug

**Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin, **AND**
- Patient must not have achieved a clinically meaningful glycaemic response with an SGLT2 inhibitor; **OR**
- Patient must have a contraindication/intolerance requiring treatment discontinuation of an SGLT2 inhibitor.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

### dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices

| 11364D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 131.40 | 25.00 | Trulicity [LY] |

## DULAGLUTIDE

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***15263***

Diabetes mellitus type 2

Treatment Phase: Subsequent PBS-prescriptions for any GLP-1 receptor agonist

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

### dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices

| 14150R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 131.40 | 25.00 | Trulicity [LY] |

## SEMAGLUTIDE

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15301***

Diabetes mellitus type 2

Treatment Phase: First PBS-prescription for this drug

**Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin, **AND**
- Patient must not have achieved a clinically meaningful glycaemic response with an SGLT2 inhibitor; **OR**
- Patient must have a contraindication/intolerance requiring treatment discontinuation of an SGLT2 inhibitor.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**semaglutide 0.68 mg/mL injection, 1 x 3 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14844G NP | 1 | 5 | 0.00 | 131.40 | 25.00 | Ozempic [NO] |

**semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12075M NP | ‡1 | 5 | 0.00 | 131.40 | 25.00 | Ozempic [NO] |

## SEMAGLUTIDE

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***15263***

Diabetes mellitus type 2

Treatment Phase: Subsequent PBS-prescriptions for any GLP-1 receptor agonist

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

**semaglutide 0.68 mg/mL injection, 1 x 3 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14846J NP | 1 | 5 | 0.00 | 131.40 | 25.00 | Ozempic [NO] |

**semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14163K NP | ‡1 | 5 | 0.00 | 131.40 | 25.00 | Ozempic [NO] |

## SEMAGLUTIDE

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***18495***

Diabetes mellitus type 2

Treatment Phase: Subsequent PBS-prescriptions for any GLP-1 receptor agonist

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Note** Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

**semaglutide 0.68 mg/mL injection, 1 x 3 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15311W NP | 2 | 5 | 0.00 | *253.44 | 25.00 | Ozempic [NO] |

**semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15322K NP | 2 | 5 | 0.00 | *253.44 | 25.00 | Ozempic [NO] |

### *Sodium-glucose co-transporter 2 (SGLT2) inhibitors*

## DAPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15047***

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**dapagliflozin 10 mg tablet, 28**

| 12823X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 52.35 | 25.00 | Forxiga [AP] |

## DAPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***18624***

Chronic kidney disease

**Clinical criteria:**

- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 20 to 90 mL/min/1.73 $m^2$ inclusive prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 45 to 90 mL/min/1.73 $m^2$ inclusive, with a urinary albumin to creatinine ratio of at least 200 mg/g (22.6 mg/mmol) prior to initiating treatment with this drug; **OR**
- Patient must have an estimated glomerular filtration rate of between 20 to 45 mL/min/1.73 $m^2$ inclusive, with any level of urinary albumin to creatinine ratio prior to initiating treatment with this drug, **AND**
- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug.

Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.

**dapagliflozin 10 mg tablet, 28**

| 13106T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 52.35 | 25.00 | Forxiga [AP] |

## DAPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15051***

Chronic heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**

- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**dapagliflozin 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14054Q NP | 2 | 5 | 0.00 | *90.34 | 25.00 | Forxiga [AP] |

## DAPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***18623***

Chronic kidney disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 20 to 90 mL/min/1.73 $m^2$ inclusive prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 45 to 90 mL/min/1.73 $m^2$ inclusive, with a urinary albumin to creatinine ratio of at least 200 mg/g (22.6 mg/mmol) prior to initiating treatment with this drug; **OR**
- Patient must have an estimated glomerular filtration rate of between 20 to 45 mL/min/1.73 $m^2$ inclusive, with any level of urinary albumin to creatinine ratio prior to initiating treatment with this drug, **AND**
- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug.

Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.

**dapagliflozin 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15257B NP | 2 | 5 | 0.00 | *90.34 | 25.00 | Forxiga [AP] |

## DAPAGLIFLOZIN

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***16220***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; unless contraindicated/intolerant, **AND**
- Patient must have cardiovascular disease; **OR**
- Patient must be at high risk of a cardiovascular event; **OR**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au.

High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

**Authority Required (STREAMLINED)**

***15311***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**

- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**dapagliflozin 10 mg tablet, 28**

| 10011X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 52.35 | 25.00 | Forxiga [AP] |

## DAPAGLIFLOZIN

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***16164***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with metformin; unless contraindicated/intolerant, **AND**
- Patient must have cardiovascular disease; **OR**
- Patient must be at high risk of a cardiovascular event; **OR**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au.

High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

**Authority Required (STREAMLINED)**

***15265***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**dapagliflozin 10 mg tablet, 28**

| 13844P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *90.34 | 25.00 | Forxiga [AP] |

## DAPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***14471***
Chronic heart failure
**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%, **AND**
- Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy), **AND**
- Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**dapagliflozin 10 mg tablet, 28**

| 14073Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 52.35 | 25.00 | Forxiga [AP] |

## DAPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***18113***
Chronic heart failure
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%, **AND**
- Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy), **AND**
- Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**dapagliflozin 10 mg tablet, 28**

| 15353C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *90.34 | 25.00 | Forxiga [AP] |

## EMPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***15047***
Chronic heart failure
**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**

- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**empagliflozin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12918X NP | 1 | 5 | 0.00 | 55.06 | 25.00 | Jardiance [BY] |

## EMPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***15051***
Chronic heart failure
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**empagliflozin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14018T NP | 2 | 5 | 0.00 | *95.76 | 25.00 | Jardiance [BY] |

## EMPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***18624***
Chronic kidney disease
**Clinical criteria:**

- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 20 to 90 mL/min/1.73 $m^2$ inclusive prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 45 to 90 mL/min/1.73 $m^2$ inclusive, with a urinary albumin to creatinine ratio of at least 200 mg/g (22.6 mg/mmol) prior to initiating treatment with this drug; **OR**
- Patient must have an estimated glomerular filtration rate of between 20 to 45 mL/min/1.73 $m^2$ inclusive, with any level of urinary albumin to creatinine ratio prior to initiating treatment with this drug, **AND**
- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug.

Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.

**empagliflozin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14092Q NP | 1 | 5 | 0.00 | 55.06 | 25.00 | Jardiance [BY] |

## EMPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***18623***

Chronic kidney disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 20 to 90 mL/min/1.73 $m^2$ inclusive prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of between 45 to 90 mL/min/1.73 $m^2$ inclusive, with a urinary albumin to creatinine ratio of at least 200 mg/g (22.6 mg/mmol) prior to initiating treatment with this drug; **OR**
- Patient must have an estimated glomerular filtration rate of between 20 to 45 mL/min/1.73 $m^2$ inclusive, with any level of urinary albumin to creatinine ratio prior to initiating treatment with this drug, **AND**
- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug.

Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.

**empagliflozin 10 mg tablet, 30**

| 15253T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *95.76 | 25.00 | Jardiance [BY] |

## EMPAGLIFLOZIN

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***16220***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; unless contraindicated/intolerant, **AND**
- Patient must have cardiovascular disease; **OR**
- Patient must be at high risk of a cardiovascular event; **OR**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au.

High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

**Authority Required (STREAMLINED)**

***15311***

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**empagliflozin 10 mg tablet, 30**

| 10206E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 55.06 | 25.00 | Jardiance [BY] |

**empagliflozin 25 mg tablet, 30**

| 10202Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 55.27 | 25.00 | Jardiance [BY] |

## EMPAGLIFLOZIN

**Note** Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

**Authority Required (STREAMLINED)**

***16164***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with metformin; unless contraindicated/intolerant, **AND**
- Patient must have cardiovascular disease; **OR**
- Patient must be at high risk of a cardiovascular event; **OR**
- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au.

High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

**Authority Required (STREAMLINED)**

***15265***

Diabetes mellitus type 2

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

**Treatment criteria:**

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

**Note** Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

**empagliflozin 10 mg tablet, 30**

| 13845Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *95.76 | 25.00 | Jardiance [BY] |

**empagliflozin 25 mg tablet, 30**

| 13920P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *96.18 | 25.00 | Jardiance [BY] |

## EMPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***14471***

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%, **AND**
- Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy), **AND**
- Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**empagliflozin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13695T NP | 1 | 5 | 0.00 | 55.06 | 25.00 | Jardiance [BY] |

## EMPAGLIFLOZIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***18113***

Chronic heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%, **AND**
- Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy), **AND**
- Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

**empagliflozin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15252R NP | 2 | 5 | 0.00 | *95.76 | 25.00 | Jardiance [BY] |

# VITAMINS

## VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO

### *Vitamin D and analogues*

## CALCITRIOL

**Authority Required (STREAMLINED)**

***5401***

Hypocalcaemia

**Clinical criteria:**

- The condition must be due to renal disease.

**Authority Required (STREAMLINED)**

***5255***

Hypoparathyroidism

**Authority Required (STREAMLINED)**

***5089***

Hypophosphataemic rickets

**Authority Required (STREAMLINED)**

***5114***

Vitamin D-resistant rickets

**Authority Required (STREAMLINED)**

***5402***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

| 2502Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 29.99 | 25.00 | [a] Calciprox [ZS] | [a] CALITROL [XT] |
| | | | | | | [a] Sical [AF] | |
| | | | [B]2.23 | 32.22 | 25.00 | [a] Rocaltrol [IX] | |

## CALCITRIOL

**Authority Required (STREAMLINED)**

***14322***

Hypocalcaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be due to renal disease.

**Authority Required (STREAMLINED)**

***14287***

Hypoparathyroidism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required (STREAMLINED)**

***14231***

Hypophosphataemic rickets

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required (STREAMLINED)**

***14296***

Vitamin D-resistant rickets

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required (STREAMLINED)**

***14259***

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

| 13457G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *45.62 | 25.00 | [a] Calciprox [ZS] | [a] CALITROL [XT] |
| | | | | | | [a] Sical [AF] | |
| | | | [B]4.46 | 50.08 | 25.00 | [a] Rocaltrol [IX] | |

## VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

### *Vitamin B1, plain*

## THIAMINE

**Authority Required (STREAMLINED)**

***5139***

Thiamine deficiency

**Clinical criteria:**

- The treatment must be for prophylaxis.

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**thiamine hydrochloride 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1070H | | | | | | |
| NP | 1 | 2 | 0.00 | 18.22 | 19.76 | Betavit [PP] |

### THIAMINE

**Authority Required (STREAMLINED)**

***14319***

Thiamine deficiency

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for prophylaxis.

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**thiamine hydrochloride 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13354W | | | | | | |
| NP | 2 | 2 | 0.00 | *22.08 | 23.62 | Betavit [PP] |

## MINERAL SUPPLEMENTS

### CALCIUM

#### *Calcium*

### CALCIUM

**Authority Required (STREAMLINED)**

***4586***

Hyperphosphataemia

**Clinical criteria:**

- The condition must be associated with chronic renal failure.

**calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11726E | | | | | | |
| NP | 2 | 1 | 0.00 | *29.96 | 25.00 | Cal-500 [PP] |

**calcium carbonate 1.5 g (calcium 600 mg) tablet, 240**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3117C | | | | | | |
| NP | 1 | 1 | 0.00 | 25.17 | 25.00 | Calci-Tab 600 [AE] |

### CALCIUM

**Authority Required (STREAMLINED)**

***14228***

Hyperphosphataemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be associated with chronic renal failure.

**calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13485R | | | | | | |
| NP | 4 | 1 | 0.00 | *45.56 | 25.00 | Cal-500 [PP] |

**calcium carbonate 1.5 g (calcium 600 mg) tablet, 240**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13547B | | | | | | |
| NP | 2 | 1 | 0.00 | *35.98 | 25.00 | Calci-Tab 600 [AE] |

### POTASSIUM

#### *Potassium*

### POTASSIUM CHLORIDE

**potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1841X | | | | | | |
| NP | 1 | 1 | 0.00 | 30.29 | 25.00 | Span-K [AS] |

## POTASSIUM CHLORIDE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200**

| 13357B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *46.22 | 25.00 | Span-K [AS] |

## POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE

**potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet, 60**

| 3012M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 34.18 | 25.00 | Chlorvescent [AS] |

## POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) effervescent tablet, 60**

| 13486T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *54.00 | 25.00 | Chlorvescent [AS] |

# OTHER MINERAL SUPPLEMENTS

### *Magnesium*

## MAGNESIUM

**Authority Required (STREAMLINED)**

***5506***

Hypomagnesaemia

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority Required (STREAMLINED)**

***5466***

Chronic renal disease

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**magnesium 37.4 mg tablet, 50**

| 5146W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.92 | 21.46 | MagMin (PBS) [BB] | Mag-Sup [PP] |

# OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

## OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

### *Amino acids and derivatives*

## BETAINE

**Authority Required**

***4599***

Homocystinuria

**Clinical criteria:**

- The treatment must be as adjunctive therapy to current standard care, **AND**
- The condition must be treated by or in consultation with a metabolic physician.

The name of the specialist must be included in the authority application.

**betaine 1 g/g powder for oral liquid, 180 g**

| 10119N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 507.69 | 25.00 | Cystadane [RJ] |

### *Various alimentary tract and metabolism products*

## GIVOSIRAN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18460***

Chronic treatment of Acute Hepatic Porphyria (AHP)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a confirmed diagnosis of AHP based on clinical features, **AND**
- Patient must have a previous result that showed a 4 times greater than the upper limit of normal (ULN) on one of the following tests: (i) urinary porphobilinogen, (ii) plasma porphobilinogen, (iii) delta-aminolevulinic acid, **AND**
- Patient must have had at least 2 porphyria attacks (requiring hospitalisation, presentation at an emergency department, or medical intervention via a porphyria clinic) within the 6 months prior to: (i) commencement of this drug; or (ii) prophylactic treatment with gonadotropin-releasing hormone analogues or hemin, **AND**
- Patient must not have previously undergone a liver transplant, **AND**
- The treatment must be initiated under the supervision of a healthcare professional experienced in the management of porphyria.

**Population criteria:**

- Patient must be at least 12 years of age.

For the purposes of administering this restriction, clinical features to confirm a diagnosis of AHP can include but are not limited to acute attacks of: abdominal, back, chest, extremities, and/or limb pain.

At the time of the authority application, prescribers should request the appropriate number of vials for a single dose based on the patient's weight, as per the TGA-approved Product Information.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) The baseline number of porphyria attacks within a defined 6-month period [dates of the 6-month period must be included].

(2) Pathology measurements that indicate 4 times greater than the ULN of one of the following tests:

(i) urinary porphobilinogen;

(ii) plasma porphobilinogen;

(iii) delta-aminolevulinic acid.

Date of pathology report and unique identifying number/code that links the pathology result to the individual patient must be included.

(3) Current weight of the patient.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority Required**

***18388***

Chronic treatment of Acute Hepatic Porphyria (AHP)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate improvement in the frequency or severity of AHP attacks from baseline while on treatment with this drug.

**Treatment criteria:**

- Must be treated by a healthcare professional experienced in the management of porphyria or in consultation with a healthcare professional experienced in the management of porphyria.

**Clinical criteria:**

- Patient must not have previously undergone a liver transplant.

**Population criteria:**

- Patient must be at least 12 years of age.

The number of AHP attacks while on treatment must be documented in the patient's medical records.

At the time of the authority application, prescribers should request the appropriate number of vials for a single dose based on the patient's weight, as per the TGA-approved Product Information.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### givosiran 189 mg/mL injection, 1 mL vial

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15289Q | 2 | 5 | 0.00 | *164,300.92 | 25.00 | Givlaari [WM] |

## LUMASIRAN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17401***

Primary hyperoxaluria type 1

Treatment Phase: Initial treatment - loading dose

**Clinical criteria:**

- The condition must be primary hyperoxaluria type 1 confirmed by genetic testing, **AND**
- Patient must have undergone treatment with pyridoxine therapy; **OR**
- Patient must have a PH1 allele that is considered not responsive to pyridoxine therapy; **OR**
- Patient must be contraindicated for pyridoxine therapy as determined by the treating or consulting clinician, **AND**
- Patient must have urinary oxalate greater than or equal to 0.70 mmol/24 h/1.73 $m^2$ measured by mean 24-h urinary oxalate excretion from a valid 24-h urine collection; **OR**
- Patient must have urinary oxalate: creatinine ratio greater than the upper limit of normal based on age on at least two of three single-void collections during screening; **OR**
- Patient must have clinical symptoms indicative of hyperoxaluria, such as (i) nephrocalcinosis; (ii) renal stones; (iii) renal impairment; (iv) systemic oxalosis, **AND**
- Patient must not have previously undergone liver transplant for primary hyperoxaluria type 1.

**Treatment criteria:**

- Must be treated by a nephrologist with experience in the management of hyperoxaluria; **OR**
- Must be treated by a paediatrician with experience in the management of hyperoxaluria; **OR**
- Must be treated by an authorised prescriber in consultation with one of the above specialty types.

At the time of the authority application, prescribers should request the appropriate number of vials based on the patient's weight, as per the TGA approved Product Information. Up to 2 repeats may be requested for initial treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### Lumasiran 94.5 mg/0.5 mL injection, 0.5 mL vial

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15052F NP | ‡5 | 2 | 0.00 | *491,157.19 | 25.00 | Oxlumo [WM] |

## LUMASIRAN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17399***

Primary hyperoxaluria type 1

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must continue to demonstrate clinical benefit as assessed by the treating physician, **AND**
- Patient must not have previously undergone liver transplant for primary hyperoxaluria type 1.

**Treatment criteria:**

- Must be treated by a nephrologist with experience in the management of hyperoxaluria; **OR**
- Must be treated by a paediatrician with experience in the management of hyperoxaluria; **OR**
- Must be treated by an authorised prescriber in consultation with one of the above specialty types.

At the time of the authority application, prescribers should request the appropriate number of vials based on the patient's weight, as per the TGA approved Product Information. Up to 1 repeat may be requested for continuing treatment.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### Lumasiran 94.5 mg/0.5 mL injection, 0.5 mL vial

| 15060P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡5 | 1 | 0.00 | *491,157.19 | 25.00 | Oxlumo [WM] |

## MIGALASTAT

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***19038***

Fabry disease

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have at least one of: (i) documented deficiency of alpha-galactosidase enzyme activity in blood, (ii) presence of genetic mutations known to result in deficiency of alpha-galactosidase enzyme activity, **AND**
- Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 $m^2$, **AND**
- Patient must be male with Fabry-related renal disease confirmed by at least one of the following: (i) abnormal albuminuria of more than 20 mcg/min, as determined by 2 separate samples at least 24 hours apart, (ii) abnormal proteinuria of more than 150 mg/24 hours, (iii) albumin:creatinine ratio greater than upper limit of normal in 2 separate samples at least 24 hours apart, (iv) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; **OR**
- Patient must be female with Fabry-related renal disease confirmed by at least one of the following: (i) proteinuria of more than 300 mg/24 hours with clinical evidence of progression, (ii) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; **OR**
- Patient must have Fabry-related cardiac disease confirmed by at least one of the following: (i) left ventricular hypertrophy, as evidenced by cardiac magnetic resonance imaging (MRI) or echocardiogram data, in the absence of hypertension, (ii) significant life-threatening arrhythmia or conduction defect, (iii) late gadolinium enhancement or a low T1 on cardiac MRI; **OR**
- Patient must have Fabry-related either: (i) ischaemic disease, (ii) cerebrovascular disease as shown on objective testing with no other cause or risk factors identified; **OR**

- Patient must have Fabry-related uncontrolled chronic pain despite the use of recommended doses of appropriate analgesia and antiseizure medications for peripheral neuropathy; **OR**
- Patient must have significant Fabry-related gastrointestinal symptoms despite the use of the recommended doses of appropriate pharmacological therapies, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of Fabry disease.

**Population criteria:**

- Patient must be at least 12 years of age.

If hypertension is present in patients relying their eligibility on Fabry-related cardiac disease, the prescriber must treat it optimally for at least 6 months prior to submitting the first PBS authority application.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***19034***

Fabry disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by migalastat, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of Fabry disease.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***18998***

Fabry disease

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Fabry disease therapy)

**Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 September 2024; **OR**
- Patient must have previously received treatment with Enzyme Replacement Therapy for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 September 2024, **AND**
- Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant prior to commencing treatment with this drug, **AND**
- Patient must have/have had an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 $m^2$ prior to commencing treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of Fabry disease.

**Population criteria:**

- Patient must be at least 12 years of age.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***19044***

Fabry disease

Treatment Phase: Switching from PBS-subsidised pegunigalsidase alfa

**Clinical criteria:**

- Patient must have received prior treatment with PBS-subsidised pegunigalsidase alfa for this condition, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 $m^2$, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have failed to demonstrate clinical improvement or stabilisation of this condition with previous PBS-subsidised treatment with this drug.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of Fabry disease.

**Population criteria:**

- Patient must be at least 12 years of age.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**migalastat 123 mg capsule, 14**

14573B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 6 | 0.00 | 28,246.21 | 25.00 | Galafold [FT] |

## SAPROPTERIN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***10076***

Hyperphenylalaninaemia

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a metabolic physician.

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

**Note** Patient will be eligible for a maximum of one PBS-subsidised prescription as initial therapy to enable their response to treatment with sapropterin to be assessed.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

10086W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 0 | 0.00 | *4,966.50 | 25.00 | Kuvan [IO] |

## SAPROPTERIN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***10390***

Hyperphenylalaninaemia

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a metabolic physician; **OR**
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

### saropterin dihydrochloride 100 mg soluble tablet, 30

10087X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | 0.00 | *4,966.50 | 25.00 | Kuvan [IO] |

NP

## SAPROPTERIN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***10355***

Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a metabolic physician; **OR**
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

### saropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets

11970B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 4,090.73 | 25.00 | Kuvan [IO] |

NP

## SAPROPTERIN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***10391***

Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a metabolic physician.

**Clinical criteria:**

- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

**Note** Patient will be eligible for a maximum of one PBS-subsidised prescription as initial therapy to enable their response to treatment with sapropterin to be assessed.

### saropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets

11973E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 4,090.73 | 25.00 | Kuvan [IO] |

## SAPROPTERIN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***13885***

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Initial treatment - responsiveness testing

**Treatment criteria:**

- Must be treated by a metabolic physician.

**Clinical criteria:**

- Patient must be untreated with this drug; **OR**
- Patient must have completed prior responsiveness testing on only 1 occasion - this occurred when the patient was less than 1 month of age, but this benefit is for a second attempt at responsiveness testing in a patient aged at least 1 month old, **AND**
- Patient must have a baseline blood phenylalanine level above 360 micromole per L and be less than one month of age; **OR**
- Patient must have a baseline blood phenylalanine level above 600 micromole per L and be more than one month of age, **AND**
- The treatment must be for the purpose of initial responsiveness testing for a period of 24 hours in a patient less than one month of age; **OR**
- The treatment must be for the purpose of initial responsiveness testing for a period of 7 days in a patient aged more than one month.

Dietary phenylalanine intake must be maintained at a constant level.

Patients or their parent/guardian should be assessed for their ability to comply with the sapropterin protocol and PKU diet prior to conducting initial responsiveness testing.

### sapropterin dihydrochloride 100 mg soluble tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11676M | 1 | 0 | 0.00 | 859.36 | 25.00 | Kuvan [IO] |

### sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11971C | 1 | 0 | 0.00 | 4,090.73 | 25.00 | Kuvan [IO] |

## SAPROPTERIN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***13880***

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a metabolic physician; **OR**
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment under the Initial treatment - responsiveness testing restriction with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug of greater than or equal to a 30% reduction in phenylalanine levels from baseline during initial responsiveness testing.

Blood phenylalanine levels must be based on measurements taken during stable periods of the condition.

Dietary phenylalanine intake must be maintained at a constant level.

**Authority Required**

***13912***

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Subsequent continuing

**Treatment criteria:**

- Must be treated by a metabolic physician; **OR**
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**

- Patient must be undergoing regular phenylalanine testing and assessment of adherence to dietary modifications.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

| 11691H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 6 | 5 | 0.00 | *4,966.50 | 25.00 | Kuvan [IO] |

**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

| 11983Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 4,090.73 | 25.00 | Kuvan [IO] |

## SAPROPTERIN

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***11836***

Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Pre-conception through to when pregnancy first becomes known

**Clinical criteria:**

- Patient must have demonstrated an adequate response to treatment with this drug at least once in a lifetime, with an adequate response defined as a reduction in phenylalanine levels from baseline during initial responsiveness testing of no less than 30%.

**Treatment criteria:**

- Must be treated by a metabolic physician; **OR**
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician, **AND**
- Patient must not be undergoing treatment with this drug under this Treatment phase, following completion of this authority application, for more than 13 cumulative months (assuming 1 month consists of 30 days), **AND**
- Patient must not be undergoing simultaneous treatment with this drug under another non-maternal PBS-listing (apply under either listing type, but not both simultaneously).

**Population criteria:**

- Patient must be actively trying to conceive.

**Note** Request an appropriate maximum quantity (with the number of packs being a whole number) to provide approximately 30 days treatment duration per dispensing, based on dosing no greater than 20 mg/kg per day.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** This PBS listing intends to subsidise up to 13 cumulative months (assuming 1 month consists of 30 days) of treatment during the pre-conception phase per known pregnancy. The time taken to conceive can vary for each patient, but where this treatment phase of 'pre-conception through to when pregnancy becomes first known' exceeds a cumulative 13 months, continued treatment beyond this time up to the point of conception, is not PBS subsidised.

13 cumulative months comprises of the time taken to achieve desired phenylalanine level control and the time taken for pregnancy to become known (e.g. If it takes 3 months to reach desired phenylalanine level control, 10 months of PBS-subsidised treatment remain in which to achieve pregnancy; if it takes only 1 month to reach desired phenylalanine level control, 12 months of PBS-subsidised treatment remain in which to achieve pregnancy)

**Authority Required**

***11960***

Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Existing pregnancy to birth

**Population criteria:**

- Patient must be pregnant.

**Clinical criteria:**

- Patient must have demonstrated an adequate response to treatment with this drug at least once in a lifetime, with an adequate response defined as a reduction in phenylalanine levels from baseline during initial responsiveness testing of no less than 30%.

**Treatment criteria:**

- Must be treated by a metabolic physician; **OR**
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician, **AND**
- Patient must not be undergoing further treatment with this drug as a PBS benefit, post-partum in the absence of actively trying to conceive a subsequent child/a known subsequent pregnancy, **AND**
- Patient must not be undergoing simultaneous treatment with this drug under another non-maternal PBS-listing (apply under either listing type, but not both simultaneously).

**Note** Request an appropriate maximum quantity (with the number of packs being a whole number) to provide approximately 30 days treatment duration per dispensing, based on dosing no greater than 20 mg/kg per day.

**Note** Request an appropriate number of repeats (whole number) relative to the expected birth date such that treatment is not continued post-partum by a whole prescription quantity. If the expected birth date is within the next 30 days at the time of the authority application, do not request repeats.

**Note** This PBS listing intends to subsidise treatment only whilst the patient is pregnant. Treatment is to be discontinued upon birth under this listing. Whilst a patient may benefit from continued treatment post-partum, continued treatment with this drug post-partum is not PBS subsidised in the absence of actively trying to conceive again/a known subsequent pregnancy.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12569M NP | 1 | 5 | 0.00 | 859.36 | 25.00 | Kuvan [IO] |

## SAPROPTERIN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Request an appropriate maximum quantity based on testing response to treatment for 7 days, with the number of packs being a whole number, based on dosing no greater than 20 mg/kg per day. Combinations of the sachets and tablets are permitted to reduce high tablet burden.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***13868***

Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

Treatment Phase: Initial treatment - responsiveness testing

**Clinical criteria:**

- The treatment must be for the purpose of ascertaining the patient's response to treatment over a period of 7 days, with the intent to then use the drug to control phenylalanine levels under the treatment phase: First continuing treatment, Indication: Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU), **AND**
- Patient must have a baseline blood phenylalanine level above 250 micromol/L prior to commencing treatment with this drug despite best efforts to rely on dietary modifications to control phenylalanine levels.

**Treatment criteria:**

- Must be treated by a metabolic physician, **AND**
- Patient must be undergoing treatment with this drug for the first time, **AND**
- Patient must not be undergoing treatment with this drug under this Treatment phase, more than once per lifetime following completion of this authority application, **AND**
- Patient must not be undergoing simultaneous treatment with this drug under another PBS-listing (apply under either listing type, but not both simultaneously).

**Population criteria:**

- Patient must be one of: (i) planning conception, (ii) pregnant.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12579C | 1 | 0 | 0.00 | 859.36 | 25.00 | Kuvan [IO] |

**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12570N | 1 | 0 | 0.00 | 4,090.73 | 25.00 | Kuvan [IO] |

## SODIUM PHENYLBUTYRATE

**Authority Required (STREAMLINED)**

***9993***

Urea cycle disorders

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have elevated ammonia levels that are not controlled with diet alone and other adjunct care alone.

An increase in the maximum quantity will be authorised to provide for up to one month's supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m$^2$/day in patients weighing more than 20 kg.

**Authority Required (STREAMLINED)**

***9919***

Urea cycle disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

An increase in the maximum quantity will be authorised to provide for up to one month's supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m$^2$/day in patients weighing more than 20 kg.

**sodium phenylbutyrate 483 mg/g granules, 174 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11865L NP | 3 | 5 | 0.00 | *1,569.96 | 25.00 | Pheburane [OH] |

## TRIENTINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***13321***

Chelation of elevated copper levels

**Clinical criteria:**

- Patient must have a diagnosis of Wilson disease, **AND**
- Patient must be intolerant to penicillamine.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner, where this authority application is to initiate treatment with this drug, of the following type: (i) gastroenterologist, (ii) hepatologist, (iii) neurologist; the authority prescription must be completed by the specialist prescriber; **OR**
- Must be treated by a medical practitioner (of any type), where this authority application is continuing established trientine treatment (of any specified salt) initiated by one of the above mentioned specialist types; **OR**
- Must be treated by a nurse practitioner where this authority application is continuing established trientine treatment (of any specified salt) initiated by one of the above mentioned specialist types.

Prior to seeking the initial authority approval, establish evidence of excess copper levels based on at least one of: (i) clinical symptoms, (ii) measured serum copper levels, (iii) measured urinary copper levels.

Document what these findings were in the patient's medical records. Do not supply them in this authority application.

Refer to the following definitions if in doubt over what constitutes an acceptable intolerance to penicillamine:

Side effects of penicillamine occurring soon after initiation (within first few weeks/months):

(i) fever, (ii) rash, (iii) enlarged lymph nodes, (iv) neutropenia, (v) thrombocytopenia, (vi) proteinuria, (vii) severe, persistent nausea.

Side effects of penicillamine developing later:

(i) nephrotic syndrome, (ii) glomerulonephritis, (iii) total bone marrow aplasia, (iv) skin changes (cutis laxa, elastosis perforans serpiginosa, pemphigus), (v) myasthenia gravis, (vi) polymyositis, (vii) Goodpasture syndrome, (viii) optic neuritis, (ix) proteinuria (1-2 grams/day or equivalent in children, depending on specialist Wilson disease and renal review), (x) haematuria (if cause unknown), (xi) thrombocytopenia/leukopenia, (xii) bleeding related to thromobocytopenia/leukopenia, (xiii) lupus-like syndrome (haematuria, proteinuria, positive antinuclear antibody), (xiv) arthralgia.

At the time of the first authority application for this drug, document the details (date of reaction, severity of reaction, dose of penicillamine, etc) of the penicillamine intolerance, if not already done, in the patient's medical records. Do not supply these details in this authority application.

**trientine dihydrochloride 250 mg capsule, 100**

| 13124R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *1,816.36 | 25.00 | [a] Trientine Dr. Reddy's [RZ] | [a] Trientine Waymade [IX] |

# BLOOD AND BLOOD FORMING ORGANS

## ANTITHROMBOTIC AGENTS

### ANTITHROMBOTIC AGENTS

#### *Vitamin K antagonists*

## WARFARIN

**Caution** The listed brands have NOT been shown to be bioequivalent and should not be interchanged.

**warfarin sodium 1 mg tablet, 50**

| 2843P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 18.95 | 20.49 | Coumadin [GO] | Marevan [GT] |

**warfarin sodium 2 mg tablet, 50**

| 2209G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 19.13 | 20.67 | Coumadin [GO] |

**warfarin sodium 3 mg tablet, 50**

| 2844Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 19.19 | 20.73 | Marevan [GT] |

**warfarin sodium 5 mg tablet, 50**

| 2211J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 19.60 | 21.14 | Coumadin [GO] | Marevan [GT] |

#### *Heparin group*

## ENOXAPARIN SODIUM

**Restricted benefit**

***4910***
Haemodialysis

**enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes**

| 13688K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 89.48 | 25.00 | [a] Enoxaject Safety-Lock [CR] | [a] Exarane Forte [JU] |
| | | | | | | [a] Exarane Forte Safety-Lock [JO] | |

**enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes**

| 13717Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 108.26 | 25.00 | [a] Enoxaject Safety-Lock [CR] | [a] Exarane Forte [JU] |
| | | | | | | [a] Exarane Forte Safety-Lock [JO] | |

## ENOXAPARIN SODIUM

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Restricted benefit**

***4910***
Haemodialysis

**enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes**

| 8716R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *63.04 | 25.00 | [a] Clexane Safety-Lock [AV] | [a] Enoxaject Safety-Lock [CR] |
| | | | | | | [a] Exarane [JU] | [a] Exarane Safety-Lock [JO] |

**enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes**

| 8639Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *68.78 | 25.00 | [a] Clexane Safety-Lock [AV] | [a] Enoxaject Safety-Lock [CR] |
| | | | | | | [a] Exarane [JU] | [a] Exarane Safety-Lock [JO] |

**enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes**

| 8640R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *108.56 | 25.00 | [a] Clexane Safety-Lock [AV] | [a] Enoxaject Safety-Lock [CR] |
| | | | | | | [a] Exarane [JU] | [a] Exarane Safety-Lock [JO] |

**enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes**

| 5434B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *114.50 | 25.00 | [a] Clexane Safety-Lock [AV] | [a] Enoxaject Safety-Lock [CR] |
| | | | | | | [a] Exarane [JU] | [a] Exarane Safety-Lock [JO] |

**enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes**

| 5435C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *148.82 | 25.00 | [a] Clexane Safety-Lock [AV] | [a] Enoxaject Safety-Lock [CR] |
| | | | | | | [a] Exarane [JU] | [a] Exarane Safety-Lock [JO] |

## ENOXAPARIN SODIUM

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Restricted benefit**

***16261***
For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

**enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes**

| 8558K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 2 | 1 | 0.00 | *63.04 | 25.00 | [a] Clexane Safety-Lock [AV] | [a] Enoxaject Safety-Lock [CR] |

| 8558K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Exarane [JU] | [a] Exarane Safety-Lock [JO] |

**enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes**

| 8510X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 2 | 1 | 0.00 | *68.78 | 25.00 | [a] Clexane Safety-Lock [AV] | [a] Enoxaject Safety-Lock [CR] |
| | | | | | | [a] Exarane [JU] | [a] Exarane Safety-Lock [JO] |

**enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes**

| 8262W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 61.46 | 25.00 | [a] Clexane Safety-Lock [AV] | [a] Enoxaject Safety-Lock [CR] |
| | | | | | | [a] Exarane [JU] | [a] Exarane Safety-Lock [JO] |

**enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes**

| 8263X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 64.43 | 25.00 | [a] Clexane Safety-Lock [AV] | [a] Enoxaject Safety-Lock [CR] |
| | | | | | | [a] Exarane [JU] | [a] Exarane Safety-Lock [JO] |

**enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes**

| 8264Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 80.77 | 25.00 | [a] Clexane Safety-Lock [AV] | [a] Enoxaject Safety-Lock [CR] |
| | | | | | | [a] Exarane [JU] | [a] Exarane Safety-Lock [JO] |

**enoxaparin sodium 120 mg/0.8 mL injection, 10 x 0.8 mL syringes**

| 13710N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 89.48 | 25.00 | [a] Clexane Forte Safety-Lock [AV] | [a] Enoxaject Safety-Lock [CR] |
| | | | | | | [a] Exarane Forte [JU] | [a] Exarane Forte Safety-Lock [JO] |

**enoxaparin sodium 150 mg/mL injection, 10 x 1 mL syringes**

| 13729N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 108.26 | 25.00 | [a] Clexane Forte Safety-Lock [AV] | [a] Enoxaject Safety-Lock [CR] |
| | | | | | | [a] Exarane Forte [JU] | [a] Exarane Forte Safety-Lock [JO] |

## HEPARIN

**heparin sodium 5000 units/0.2 mL injection, 5 x 0.2 mL ampoules**

| 1466E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 44.24 | 25.00 | DBL Heparin Sodium [PF] |

### *Platelet aggregation inhibitors excl. heparin*

## ASPIRIN

**Restricted benefit**

***5884***

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**aspirin 100 mg tablet, 112**

| 8202Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 16.31 | 17.85 | Spren 100 [OW] |

## CLOPIDOGREL

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**clopidogrel 75 mg tablet, 28**

| 8358X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.40 | 19.94 | [a] Blooms Clopidogrel [BG] | [a] Clopidogrel Lupin [GQ] |
| | | | | | | [a] Clopidogrel Sandoz Pharma [HX] | [a] Clopidogrel Winthrop [WA] |
| | | | | | | [a] Iscover [AV] | [a] Piax [AF] |
| | | | | | | [a] Plavicor 75 [CR] | |

**clopidogrel 75 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9354H | | | | | | | |
| NP | 1 | 5 | 0.00 | 18.40 | 19.94 | [a] CLOPIDOGREL-WGR [WG] | [a] Clovix 75 [RW] |
| | | | | | | [a] Plidogrel [RF] | |

## CLOPIDOGREL

**Note** Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**clopidogrel 75 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13365K | | | | | | | |
| NP | 2 | 5 | 0.00 | *22.44 | 23.98 | [a] CLOPIDOGREL-WGR [WG] | [a] Clovix 75 [RW] |
| | | | | | | [a] Plidogrel [RF] | |

**clopidogrel 75 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13399F | | | | | | | |
| NP | 2 | 5 | 0.00 | *22.44 | 23.98 | [a] Blooms Clopidogrel [BG] | [a] Clopidogrel Lupin [GQ] |
| | | | | | | [a] Clopidogrel Sandoz Pharma [HX] | [a] Clopidogrel Winthrop [WA] |
| | | | | | | [a] Iscover [AV] | [a] Piax [AF] |
| | | | | | | [a] Plavicor 75 [CR] | |

## CLOPIDOGREL + ASPIRIN

**clopidogrel 75 mg + aspirin 100 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9296G | | | | | | | |
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APX-Clopidogrel/Aspirin 75/100 [TY] | [a] DuoCover [AV] |
| | | | | | | [a] DuoPlidogrel [XT] | [a] Piax Plus Aspirin [AF] |

## CLOPIDOGREL + ASPIRIN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**clopidogrel 75 mg + aspirin 100 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13427Q | | | | | | | |
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APX-Clopidogrel/Aspirin 75/100 [TY] | [a] DuoCover [AV] |
| | | | | | | [a] DuoPlidogrel [XT] | [a] Piax Plus Aspirin [AF] |

## PRASUGREL

**Authority Required (STREAMLINED)**

***16443***

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**

- The treatment must be in combination with aspirin, **AND**
- Patient must have percutaneous coronary intervention planned; **OR**
- Patient must have previously undergone percutaneous coronary intervention, **AND**
- Patient must not have a known history of either: (i) stroke, (ii) transient ischaemic attack, **AND**
- The treatment must be ceased if a percutaneous coronary intervention is not performed.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**Population criteria:**

- Patient must be at least 18 years of age.

Patient must be treated with the recommended maintenance dose of prasugrel according to the TGA-approved Product Information.

**prasugrel 5 mg tablet, 28**

| 14818X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 63.64 | 25.00 | Prasugrel Lupin [GQ] |

**prasugrel 10 mg tablet, 28**

| 14796R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 69.12 | 25.00 | Prasugrel Lupin [GQ] |

## TICAGRELOR

**Authority Required (STREAMLINED)**

***5746***

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**

- The treatment must be in combination with aspirin.

**ticagrelor 90 mg tablet, 56**

| 1418P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 89.83 | 25.00 | [a] ARX-TICAGRELOR [XT] | [a] Brilinta [AP] |
| | | | | | | [a] Pharmacor Ticagrelor [CR] | [a] Ticagrelor Dr.Reddy's [RZ] |
| | | | | | | [a] Ticagrelor Lupin [GQ] | [a] Ticagrelor Sandoz [SZ] |
| | | | | | | [a] Ticagrelor SUN [RA] | [a] Ticagrelor Viatris [AF] |
| | | | | | | [a] TICALOR [BZ] | [a] Tirela [NB] |

## TICAGRELOR

**Authority Required (STREAMLINED)**

***14240***

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with aspirin.

**ticagrelor 90 mg tablet, 56**

| 13524T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *167.84 | 25.00 | [a] ARX-TICAGRELOR [XT] | [a] Brilinta [AP] |
| | | | | | | [a] Pharmacor Ticagrelor [CR] | [a] Ticagrelor Dr.Reddy's [RZ] |
| | | | | | | [a] Ticagrelor Lupin [GQ] | [a] Ticagrelor Sandoz [SZ] |
| | | | | | | [a] Ticagrelor SUN [RA] | [a] Ticagrelor Viatris [AF] |
| | | | | | | [a] TICALOR [BZ] | [a] Tirela [NB] |

## TIROFIBAN

**Authority Required (STREAMLINED)**

***16123***

High risk of unstable angina

**Clinical criteria:**

- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have pain lasting longer than 20 minutes.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***16147***

High risk of unstable angina

**Clinical criteria:**

- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***16063***

Non-Q-wave myocardial infarction

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**tirofiban 12.5 mg/50 mL injection, 50 mL vial**

| 8350L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 179.21 | 25.00 | [a] Aggrastat [AS] | [a] Tirofiban Juno [JU] |

## *Direct thrombin inhibitors*

### BIVALIRUDIN

**Authority Required (STREAMLINED)**

***4919***

Coronary artery disease

**Treatment criteria:**

- Patient must be undergoing percutaneous coronary intervention.

**bivalirudin 250 mg injection, 1 vial**

| 8844L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 316.41 | 25.00 | [a] BIVALIRUDIN ARX [XT] | [a] BIVALIRUDIN MEDSURGE [DZ] |

### DABIGATRAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***4269***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**dabigatran etexilate 110 mg capsule, 60**

| 2753X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 42.96 | 25.00 | [a] ARX-Dabigatran [XT] | [a] Dabigatran Sandoz [SZ] |
| | | | | | | [a] Dabigatran Viatris [AF] | [a] PHARMACOR DABIGATRAN [CR] |
| | | | [B]7.16 | 50.12 | 25.00 | [a] Pradaxa [BY] | |

**dabigatran etexilate 150 mg capsule, 60**

| 2769R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 42.74 | 25.00 | [a] ARX-Dabigatran [XT] | [a] Dabigatran Sandoz [SZ] |
| | | | | | | [a] Dabigatran Viatris [AF] | [a] PHARMACOR DABIGATRAN [CR] |
| | | | [B]7.16 | 49.90 | 25.00 | [a] Pradaxa [BY] | |

### DABIGATRAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***4369***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 20 days supply to complete a course of treatment.

**dabigatran etexilate 75 mg capsule, 10**

| 9318K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *28.72 | 25.00 | PHARMACOR DABIGATRAN [CR] |

**dabigatran etexilate 110 mg capsule, 10**

| 9319L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *23.98 | 25.00 | Pradaxa [BY] |

## DABIGATRAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***4402***
Prevention of venous thromboembolism
**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

**dabigatran etexilate 75 mg capsule, 60**

| 9320M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 57.42 | 25.00 | [a] ARX-Dabigatran [XT] | [a] Dabigatran Viatris [AF] |
| | | | | | | [a] PHARMACOR DABIGATRAN [CR] | [a] Pradaxa [BY] |

**dabigatran etexilate 110 mg capsule, 60**

| 9321N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 42.96 | 25.00 | [a] ARX-Dabigatran [XT] | [a] Dabigatran Sandoz [SZ] |
| | | | | | | [a] Dabigatran Viatris [AF] | [a] PHARMACOR DABIGATRAN [CR] |
| | | | [B]7.16 | 50.12 | 25.00 | [a] Pradaxa [BY] | |

## DABIGATRAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***4381***
Prevention of venous thromboembolism
**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**Clinical criteria:**

- Patient must require up to 10 days of therapy.

**dabigatran etexilate 75 mg capsule, 10**

| 9322P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *28.72 | 25.00 | PHARMACOR DABIGATRAN [CR] |

**dabigatran etexilate 110 mg capsule, 10**

| 9323Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *23.98 | 25.00 | Pradaxa [BY] |

## DABIGATRAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***14301***
Prevention of stroke or systemic embolism
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

**dabigatran etexilate 110 mg capsule, 60**

| 13523R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *71.56 | 25.00 | [a] ARX-Dabigatran [XT] | [a] Dabigatran Sandoz [SZ] |
| | | | | | | [a] Dabigatran Viatris [AF] | [a] PHARMACOR DABIGATRAN [CR] |
| | | | [B]14.32 | 85.88 | 25.00 | [a] Pradaxa [BY] | |

**dabigatran etexilate 150 mg capsule, 60**

| 13489Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *71.12 | 25.00 | [a] ARX-Dabigatran [XT] | [a] Dabigatran Sandoz [SZ] |
| | | | | | | [a] Dabigatran Viatris [AF] | [a] PHARMACOR DABIGATRAN [CR] |
| | | | [B]14.32 | 85.44 | 25.00 | [a] Pradaxa [BY] | |

## *Direct factor Xa inhibitors*

### APIXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***4402***
Prevention of venous thromboembolism
**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

**apixaban 2.5 mg tablet, 60**

| 5061J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 54.88 | 25.00 | [a] Apexa [CR] | [a] Apixaban-APX [XW] |
| | | | | | | [a] Apixaban Dr.Reddy's [RI] | [a] Apixaban Lupin [GQ] |
| | | | | | | [a] Apixaban Sandoz [SZ] | [a] Apixaban Viatris [AF] |
| | | | | | | [a] APIXABAN-WGR [WG] | [a] APO-Apixaban [TX] |
| | | | | | | [a] Cip Apixaban 2.5 [LR] | [a] Eliquis [XT] |
| | | | | | | [a] MSN-APIXABAN [VM] | |

### APIXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***4269***
Prevention of stroke or systemic embolism
**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Authority Required (STREAMLINED)**
***4132***
Prevention of recurrent venous thromboembolism
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have a history of venous thromboembolism.

**apixaban 2.5 mg tablet, 60**

| 2744K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 54.88 | 25.00 | [a] Apexa [CR] | [a] Apixaban-APX [XW] |
| | | | | | | [a] Apixaban Dr.Reddy's [RI] | [a] Apixaban Lupin [GQ] |
| | | | | | | [a] Apixaban Sandoz [SZ] | [a] Apixaban Viatris [AF] |

| 2744K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] APIXABAN-WGR [WG] | [a] APO-Apixaban [TX] |
| | | | | | | [a] Cip Apixaban 2.5 [LR] | [a] Eliquis [XT] |
| | | | | | | [a] MSN-APIXABAN [VM] | |

## APIXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***4382***
Prevention of venous thromboembolism
**Treatment criteria:**
- Patient must be undergoing total knee replacement.

**Clinical criteria:**
- Patient must require up to 15 days of therapy.

**Authority Required (STREAMLINED)**
***4409***
Prevention of venous thromboembolism
**Treatment criteria:**
- Patient must be undergoing total hip replacement.

**Clinical criteria:**
- Patient must require up to 15 days supply to complete a course of treatment.

### apixaban 2.5 mg tablet, 30

| 5054B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 34.63 | 25.00 | [a] Apexa [CR] | [a] Apixaban Dr.Reddy's [RI] |
| | | | | | | [a] Cip Apixaban 2.5 [LR] | [a] Eliquis [XT] |
| | | | | | | [a] MSN-APIXABAN [VM] | |

## APIXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***4381***
Prevention of venous thromboembolism
**Treatment criteria:**
- Patient must be undergoing total knee replacement.

**Clinical criteria:**
- Patient must require up to 10 days of therapy.

**Authority Required (STREAMLINED)**
***4359***
Prevention of venous thromboembolism
**Treatment criteria:**
- Patient must be undergoing total hip replacement.

**Clinical criteria:**
- Patient must require up to 10 days supply to complete a course of treatment.

### apixaban 2.5 mg tablet, 20

| 5500L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 27.87 | 25.00 | [a] Apexa [CR] | [a] Apixaban-APX [XW] |
| | | | | | | [a] Apixaban Dr.Reddy's [RI] | [a] Cip Apixaban 2.5 [LR] |
| | | | | | | [a] Eliquis [XT] | [a] MSN-APIXABAN [VM] |

## APIXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***14301***
Prevention of stroke or systemic embolism
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**

- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Authority Required (STREAMLINED)**

***14300***

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a history of venous thromboembolism.

**apixaban 2.5 mg tablet, 60**

| 13464P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *95.40 | 25.00 | [a] Apexa [CR] | [a] Apixaban-APX [XW] |
| | | | | | | [a] Apixaban Dr.Reddy's [RI] | [a] Apixaban Lupin [GQ] |
| | | | | | | [a] Apixaban Sandoz [SZ] | [a] Apixaban Viatris [AF] |
| | | | | | | [a] APIXABAN-WGR [WG] | [a] APO-Apixaban [TX] |
| | | | | | | [a] Cip Apixaban 2.5 [LR] | [a] Eliquis [XT] |
| | | | | | | [a] MSN-APIXABAN [VM] | |

## APIXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***4269***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Authority Required (STREAMLINED)**

***18513***

Deep vein thrombosis

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority Required (STREAMLINED)**

***18522***

Pulmonary embolism

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**apixaban 5 mg tablet, 60**

| 2735Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 53.79 | 25.00 | [a] Apexa [CR] | [a] Apixaban-APX [XW] |
| | | | | | | [a] Apixaban Dr.Reddy's [RI] | [a] Apixaban Lupin [GQ] |
| | | | | | | [a] Apixaban Sandoz [SZ] | [a] Apixaban Viatris [AF] |
| | | | | | | [a] APIXABAN-WGR [WG] | [a] APO-Apixaban [TX] |
| | | | | | | [a] Cip Apixaban 5 [LR] | [a] Eliquis [XT] |
| | | | | | | [a] MSN-APIXABAN [VM] | |

## APIXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***14301***
Prevention of stroke or systemic embolism
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Authority Required (STREAMLINED)**
***18525***
Deep vein thrombosis
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority Required (STREAMLINED)**
***18527***
Pulmonary embolism
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic pulmonary embolism.

### apixaban 5 mg tablet, 60

| 13525W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *93.22 | 25.00 | [a] Apexa [CR] | [a] Apixaban-APX [XW] |
| | | | | | | [a] Apixaban Dr.Reddy's [RI] | [a] Apixaban Lupin [GQ] |
| | | | | | | [a] Apixaban Sandoz [SZ] | [a] Apixaban Viatris [AF] |
| | | | | | | [a] APIXABAN-WGR [WG] | [a] APO-Apixaban [TX] |
| | | | | | | [a] Cip Apixaban 5 [LR] | [a] Eliquis [XT] |
| | | | | | | [a] MSN-APIXABAN [VM] | |

## RIVAROXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***4402***
Prevention of venous thromboembolism
**Treatment criteria:**

- Patient must be undergoing total hip replacement.

**Clinical criteria:**

- Patient must require up to 30 days supply to complete a course of treatment.

### rivaroxaban 10 mg tablet, 15

| 9466F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 23.86 | 25.00 | [a] APO-Rivaroxaban [TX] | [a] ARX-Rivaroxaban 10 [XT] |
| | | | | | | [a] RIVAXIB [MQ] | [a] Xarelto [AF] |
| | | | | | | [a] XAREMED [DZ] | |

### rivaroxaban 10 mg tablet, 30

| 9467G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 33.36 | 25.00 | [a] APO-Rivaroxaban [TX] | [a] ARX-Rivaroxaban 10 [XT] |

| 9467G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Blooms The Chemist Rivaroxaban [BG] | [a] iXarola [AL] |
| | | | | | | [a] Rivarelto [XW] | [a] Rivaroxaban Dr.Reddy's [RZ] |
| | | | | | | [a] Rivaroxaban Lupin [GQ] | [a] Rivaroxaban Sandoz [SZ] |
| | | | | | | [a] Rivaroxaban-Teva [TB] | [a] RIVAXIB [MQ] |
| | | | | | | [a] Rivoxa [CR] | [a] TROXA [XG] |
| | | | | | | [a] Xarelto [AF] | [a] XAREMED [DZ] |

## RIVAROXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***4382***
Prevention of venous thromboembolism
**Treatment criteria:**
- Patient must be undergoing total knee replacement.

**Clinical criteria:**
- Patient must require up to 15 days of therapy.

### rivaroxaban 10 mg tablet, 15

| 9469J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 23.86 | 25.00 | [a] APO-Rivaroxaban [TX] | [a] ARX-Rivaroxaban 10 [XT] |
| | | | | | | [a] RIVAXIB [MQ] | [a] Xarelto [AF] |
| | | | | | | [a] XAREMED [DZ] | |

## RIVAROXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***4132***
Prevention of recurrent venous thromboembolism
Treatment Phase: Continuing treatment
**Clinical criteria:**
- Patient must have a history of venous thromboembolism.

### rivaroxaban 10 mg tablet, 30

| 11633G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 33.36 | 25.00 | [a] APO-Rivaroxaban [TX] | [a] ARX-Rivaroxaban 10 [XT] |
| | | | | | | [a] Blooms The Chemist Rivaroxaban [BG] | [a] iXarola [AL] |
| | | | | | | [a] Rivarelto [XW] | [a] Rivaroxaban Dr.Reddy's [RZ] |
| | | | | | | [a] Rivaroxaban Lupin [GQ] | [a] Rivaroxaban Sandoz [SZ] |
| | | | | | | [a] Rivaroxaban-Teva [TB] | [a] RIVAXIB [MQ] |
| | | | | | | [a] Rivoxa [CR] | [a] TROXA [XG] |
| | | | | | | [a] Xarelto [AF] | [a] XAREMED [DZ] |

## RIVAROXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***11013***
Chronic stable atherosclerotic disease
Treatment Phase: Initial treatment
**Clinical criteria:**
- The treatment must be in combination with aspirin, but not with any other anti-platelet therapy, **AND**
- Patient must have a diagnosis of coronary artery disease in addition to at least one of the following risk factors: (i) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (ii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iii) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent; **OR**
- Patient must have a diagnosis of peripheral artery disease in addition to at least one of the following risk factors: (i) concomitant coronary artery disease (ii) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (iii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iv) diabetes mellitus

combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent, **AND**

- Patient must have at least one of the following if coronary artery disease is present: (i) a previous multi-vessel coronary revascularisation procedure (ii) significant stenosis in at least 2 coronary arteries (iii) a previous single vessel coronary revascularisation procedure with significant stenosis in more than 1 coronary artery; **OR**
- Patient must have at least one of the following if peripheral arterial disease is present: (i) a previous peripheral/carotid artery revascularisation intervention (ii) intermittent claudication with an ankle-brachial index less than 0.9 (iii) asymptomatic carotid artery stenosis greater than 50%, **AND**
- The condition must be diagnosed by at least one of: (i) invasive (selective) angiography (ii) non-invasive imaging (i.e. CT scan, ultrasound) (iii) ankle-brachial index measurement in the case of peripheral arterial disease with intermittent claudication, **AND**
- Patient must have clinical findings/observations by the treating physician that exclude each of the following: (i) high risk of bleeding (ii) prior stroke within one month of treatment initiation (iii) prior haemorrhagic / lacunar stroke (iv) severe heart failure with a known ejection fraction less than 30% (v) New York Heart Association class III to IV heart failure symptoms (i.e. symptoms corresponding to moderate to severe limitation on physical activity, whereby any of fatigue/palpitations/dyspnoea occur upon zero to minimal activity) (vi) an estimated glomerular filtration rate less than 15 mL/minute (vii) a requirement for dual antiplatelet therapy (viii) a requirement for non-acetylsalicylic acid antiplatelet therapy (ix) a requirement for a higher dose of oral anticoagulant therapy.

**Treatment criteria:**

- Must be treated by a specialist physician; **OR**
- Must be treated by a physician who has consulted a specialist physician.

### rivaroxaban 2.5 mg tablet, 60

12197Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 31.14 | 25.00 | [a] APO-Rivaroxaban [TX] | [a] Rivaroxaban Lupin [GQ] |
| | | | | | [a] Rivaroxaban Sandoz [SZ] | [a] Rivaroxaban-Teva [TB] |
| | | | | | [a] RIVOXA [CR] | [a] Xarelto [AF] |

## RIVAROXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***14300***

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a history of venous thromboembolism.

### rivaroxaban 10 mg tablet, 30

13521P

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *52.36 | 25.00 | [a] APO-Rivaroxaban [TX] | [a] ARX-Rivaroxaban 10 [XT] |
| | | | | | [a] Blooms The Chemist Rivaroxaban [BG] | [a] iXarola [AL] |
| | | | | | [a] Rivarelto [XW] | [a] Rivaroxaban Dr.Reddy's [RZ] |
| | | | | | [a] Rivaroxaban Lupin [GQ] | [a] Rivaroxaban Sandoz [SZ] |
| | | | | | [a] Rivaroxaban-Teva [TB] | [a] RIVAXIB [MQ] |
| | | | | | [a] Rivoxa [CR] | [a] TROXA [XG] |
| | | | | | [a] Xarelto [AF] | [a] XAREMED [DZ] |

## RIVAROXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form rivaroxaban 15 mg capsule and rivaroxaban 15 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

**Authority Required (STREAMLINED)**

***4269***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

**rivaroxaban 15 mg tablet, 28**

| 2691P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 31.10 | 25.00 | [a] APO-Rivaroxaban [TX] | [a] ARX-Rivaroxaban 15 [XT] |
| | | | | | | [a] Blooms The Chemist Rivaroxaban [BG] | [a] iXarola [AL] |
| | | | | | | [a] Rivarelto [XW] | [a] Rivaroxaban Dr.Reddy's [RZ] |
| | | | | | | [a] Rivaroxaban Lupin [GQ] | [a] Rivaroxaban Sandoz [SZ] |
| | | | | | | [a] Rivaroxaban-Teva [TB] | [a] RIVAXIB [MQ] |
| | | | | | | [a] Rivoxa [CR] | [a] TROXA [XG] |
| | | | | | | [a] Xarelto [AF] | [a] XAREMED [DZ] |

**Rivaroxaban 15 mg capsule, 28**

| 15037K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 31.10 | 25.00 | [a] Relaban [NB] |

## RIVAROXABAN

**Note** Treatment may be continued by a non-specialist prescriber without need for consultation with a specialist.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***10992***
Chronic stable atherosclerotic disease
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.

**rivaroxaban 2.5 mg tablet, 60**

| 12192Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 31.14 | 25.00 | [a] APO-Rivaroxaban [TX] | [a] Rivaroxaban Lupin [GQ] |
| | | | | | | [a] Rivaroxaban Sandoz [SZ] | [a] Rivaroxaban-Teva [TB] |
| | | | | | | [a] RIVOXA [CR] | [a] Xarelto [AF] |

## RIVAROXABAN

**Note** Treatment may be continued by a non-specialist prescriber without need for consultation with a specialist.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***14298***
Chronic stable atherosclerotic disease
Treatment Phase: Continuing treatment
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.

**rivaroxaban 2.5 mg tablet, 60**

| 13366L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *47.92 | 25.00 | [a] APO-Rivaroxaban [TX] | [a] Rivaroxaban Lupin [GQ] |
| | | | | | | [a] Rivaroxaban Sandoz [SZ] | [a] Rivaroxaban-Teva [TB] |
| | | | | | | [a] RIVOXA [CR] | [a] Xarelto [AF] |

## RIVAROXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Pharmaceutical benefits that have the form rivaroxaban 15 mg capsule and rivaroxaban 15 mg tablet are equivalent for the purposes of substitution, where the pack size is the same.

**Authority Required (STREAMLINED)**
***14301***
Prevention of stroke or systemic embolism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

### rivaroxaban 15 mg tablet, 28

| 13463N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *47.84 | 25.00 | [a] APO-Rivaroxaban [TX] | [a] ARX-Rivaroxaban 15 [XT] |
| | | | | | | [a] Blooms The Chemist Rivaroxaban [BG] | [a] iXarola [AL] |
| | | | | | | [a] Rivarelto [XW] | [a] Rivaroxaban Dr.Reddy's [RZ] |
| | | | | | | [a] Rivaroxaban Lupin [GQ] | [a] Rivaroxaban Sandoz [SZ] |
| | | | | | | [a] Rivaroxaban-Teva [TB] | [a] RIVAXIB [MQ] |
| | | | | | | [a] Rivoxa [CR] | [a] TROXA [XG] |
| | | | | | | [a] Xarelto [AF] | [a] XAREMED [DZ] |

### Rivaroxaban 15 mg capsule, 28

| 14969W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *47.84 | 25.00 | [a] Relaban [NB] |

## RIVAROXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***4098***

Deep vein thrombosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority Required (STREAMLINED)**

***5098***

Pulmonary embolism

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

### rivaroxaban 15 mg tablet, 42

| 2160Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 39.48 | 25.00 | [a] APO-Rivaroxaban [TX] | [a] ARX-Rivaroxaban 15 [XT] |
| | | | | | | [a] Blooms The Chemist Rivaroxaban [BG] | [a] Rivarelto [XW] |
| | | | | | | [a] Rivaroxaban Lupin [GQ] | [a] Rivaroxaban Sandoz [SZ] |
| | | | | | | [a] Rivaroxaban-Teva [TB] | [a] RIVAXIB [MQ] |
| | | | | | | [a] Rivoxa [CR] | [a] Xarelto [AF] |
| | | | | | | [a] XAREMED [DZ] | |

## RIVAROXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form rivaroxaban 20 mg capsule and rivaroxaban 20 mg tablet are equivalent for the purposes of substitution.

**Authority Required (STREAMLINED)**

***4099***

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority Required (STREAMLINED)**

***4132***

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a history of venous thromboembolism.

**Authority Required (STREAMLINED)**

***4268***

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have confirmed acute symptomatic pulmonary embolism.

**Authority Required (STREAMLINED)**

***4269***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**rivaroxaban 20 mg tablet, 28**

| 2268J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 30.89 | 25.00 | [a] APO-Rivaroxaban [TX] | [a] ARX-Rivaroxaban 20 [XT] |
| | | | | | | [a] Blooms The Chemist Rivaroxaban [BG] | [a] iXarola [AL] |
| | | | | | | [a] Rivarelto [XW] | [a] Rivaroxaban Dr.Reddy's [RZ] |
| | | | | | | [a] Rivaroxaban Lupin [GQ] | [a] Rivaroxaban Sandoz [SZ] |
| | | | | | | [a] Rivaroxaban-Teva [TB] | [a] RIVAXIB [MQ] |
| | | | | | | [a] Rivoxa [CR] | [a] TROXA [XG] |
| | | | | | | [a] Xarelto [AF] | [a] XAREMED [DZ] |

**Rivaroxaban 20 mg capsule, 28**

| 15017J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 30.89 | 25.00 | [a] Relaban [NB] |

## RIVAROXABAN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form rivaroxaban 20 mg capsule and rivaroxaban 20 mg tablet are equivalent for the purposes of substitution.

**Authority Required (STREAMLINED)**

***14264***

Deep vein thrombosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic deep vein thrombosis, **AND**
- Patient must not have symptomatic pulmonary embolism.

**Authority Required (STREAMLINED)**

***14300***

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a history of venous thromboembolism.

**Authority Required (STREAMLINED)**

***14318***

Pulmonary embolism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have confirmed acute symptomatic pulmonary embolism.

**Authority Required (STREAMLINED)**

***14301***

Prevention of stroke or systemic embolism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have non-valvular atrial fibrillation, **AND**
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

**rivaroxaban 20 mg tablet, 28**

| 13462M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *47.42 | 25.00 | [a] APO-Rivaroxaban [TX] | [a] ARX-Rivaroxaban 20 [XT] |
| | | | | | | [a] Blooms The Chemist Rivaroxaban [BG] | [a] iXarola [AL] |
| | | | | | | [a] Rivarelto [XW] | [a] Rivaroxaban Dr.Reddy's [RZ] |
| | | | | | | [a] Rivaroxaban Lupin [GQ] | [a] Rivaroxaban Sandoz [SZ] |
| | | | | | | [a] Rivaroxaban-Teva [TB] | [a] RIVAXIB [MQ] |
| | | | | | | [a] Rivoxa [CR] | [a] TROXA [XG] |
| | | | | | | [a] Xarelto [AF] | [a] XAREMED [DZ] |

**Rivaroxaban 20 mg capsule, 28**

| 14994E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *47.42 | 25.00 | [a] Relaban [NB] |

### *Other antithrombotic agents*

## FONDAPARINUX

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***5781***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing major hip surgery.

**Authority Required (STREAMLINED)**

***5808***

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**fondaparinux sodium 2.5 mg/0.5 mL injection, 2 x 0.5 mL syringes**

| 8775W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3.5 | 0 | 0.00 | *115.63 | 25.00 | Arixtra [AS] |

# ANTIHEMORRHAGICS

## ANTIFIBRINOLYTICS

### *Amino acids*

### TRANEXAMIC ACID

**tranexamic acid 500 mg tablet, 100**

| 2180R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 39.23 | 25.00 | [a] APO-Tranexamic Acid [TX] | [a] ARX-TRANEXAMIC ACID [XT] |
| | | | | | | [a] Tranexamic Acid Lupin [GQ] | [a] Tranexamic Acid Waymade [IX] |
| | | | [B]8.06 | 47.29 | 25.00 | [a] Cyklokapron [PF] | |

## ANTIANEMIC PREPARATIONS

### IRON PREPARATIONS

#### *Iron bivalent, oral preparations*

### FERROUS FUMARATE

**Restricted benefit**

***6812***

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**ferrous fumarate 200 mg (iron 65.7 mg) tablet, 60**

| 8985X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 20.50 | 22.04 | Ferro-tab [AE] |

### FERROUS SULFATE

**ferrous sulfate heptahydrate 30 mg/mL (iron 6 mg/mL) oral liquid, 250 mL**

| 8815Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | 0.00 | 23.73 | 25.00 | Ferro-Liquid [AE] |

#### *Iron, parenteral preparations*

### FERRIC CARBOXYMALTOSE

**iron (as ferric carboxymaltose) 500 mg/10 mL injection, 10 mL vial**

| 10104T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 2 | 1 | 0.00 | *99.82 | 25.00 | [a] Ferinject [XW] | [a] FERIVO [XT] |
| | | | | | | [a] FERRICARBO [RZ] | [a] Ferric Carboxymaltose-Teva [TB] |
| | | | | | | [a] Ferrive [AF] | |

**iron (as ferric carboxymaltose) 1 g/20 mL injection, 20 mL vial**

| 11702X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 99.82 | 25.00 | [a] Ferinject [XW] | [a] FERIVO [XT] |
| | | | | | | [a] FERRICARBO [RZ] | [a] Ferric Carboxymaltose-Teva [TB] |
| | | | | | | [a] Ferrive [AF] | |

### FERRIC DERISOMALTOSE

**Note** Special Pricing Arrangements apply.

**iron (as ferric derisomaltose) 500 mg/5 mL injection, 5 mL vial**

| 11615H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 0 | 0.00 | *412.62 | 25.00 | Monofer [FK] |

**iron (as ferric derisomaltose) 1 g/10 mL injection, 10 mL vial**

| 12049E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 278.20 | 25.00 | Monofer [FK] |

### IRON POLYMALTOSE

**iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules**

| 2593L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 35.22 | 25.00 | Ferrosig [SI] |

### IRON POLYMALTOSE

**Authority Required (STREAMLINED)**

***4302***

Iron deficiency anaemia

**Treatment criteria:**

- Patient must be undergoing chronic haemodialysis.

**iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2805P NP | 1 | 5 | 0.00 | 35.22 | 25.00 | Ferrosig [SI] |

## IRON SUCROSE

**iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10229J NP | 1 | 0 | 0.00 | 39.65 | 25.00 | Venofer [CS] |

## IRON SUCROSE

**Authority Required (STREAMLINED)**

***4302***

Iron deficiency anaemia

**Treatment criteria:**

- Patient must be undergoing chronic haemodialysis.

**iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8807M NP | 1 | 5 | 0.00 | 39.65 | 25.00 | Venofer [CS] |

### *Iron in combination with folic acid*

## FERROUS FUMARATE + FOLIC ACID

**Restricted benefit**

***6812***

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**ferrous fumarate 310 mg (iron 100 mg) + folic acid 350 microgram tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9011G NP MW | 1 | 1 | 0.00 | 21.44 | 22.98 | Ferro-f-tab [AE] |

## VITAMIN B12 AND FOLIC ACID

### *Vitamin B12 (cyanocobalamin and analogues)*

## HYDROXOCOBALAMIN

**Note** One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B12 deficiencies.

**Note** Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

**Restricted benefit**

***16288***

Pernicious anaemia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife where patient care is being shared with a medical practitioner.

**Restricted benefit**

***16289***

Proven vitamin B12 deficiencies other than pernicious anaemia

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife where patient care is being shared with a medical practitioner.

**Restricted benefit**

***16269***

Anaemias associated with vitamin B12 deficiency

**Clinical criteria:**

- Patient must have had a gastrectomy, **AND**
- The treatment must be for prophylaxis.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife where patient care is being shared with a medical practitioner.

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

| 2162T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 18.57 | 20.11 | [a] Cobal-B12 [JU] | [a] Vita-B12 [GH] |

**hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

| 9048F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 18.57 | 20.11 | [a] Hydroxo-B12 [AS] | [a] Neo-B12 [PF] |

### *Folic acid and derivatives*

## FOLIC ACID

**Restricted benefit**

***5824***

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**folic acid 500 microgram tablet, 100**

| 2958Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 2 | 0 | 0.00 | *18.62 | 20.16 | [a] Foltabs 500 [PP] | [a] Megafol 0.5 [AF] |

## FOLIC ACID

**Note** The 5 mg strength tablet should be used in malabsorption states only.

**Restricted benefit**

***5824***

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**folic acid 5 mg tablet, 100**

| 1437P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 2 | 1 | 0.00 | *20.68 | 22.22 | Megafol 5 [AF] |

# BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

## BLOOD AND RELATED PRODUCTS

### *Blood substitutes and plasma protein fractions*

## HYDROXYETHYL STARCH 130/0.4 + SODIUM CHLORIDE

**HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1**

| 9487H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 0 | 0.00 | *35.70 | 25.00 | Voluven 6% [PK] |

# OTHER HEMATOLOGICAL AGENTS

## OTHER HEMATOLOGICAL AGENTS

### *Drugs used in hereditary angioedema*

## GARADACIMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18496***

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Initial 1: New patient (commencing with no previous treatment with C1-INH for routine prophylaxis), Initial 2: New patient (commencing from National Blood Authority-funded C1-INH) or Initial 3: New patient (transitioning from PBS-subsidised lanadelumab) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1: New patient (commencing with no previous treatment with C1-INH for routine prophylaxis) restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2: New patient (commencing from National Blood Authority-funded C1-INH) restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3: New patient (transitioning from PBS-subsidised lanadelumab) restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction, **AND**
- The treatment must not be used in combination with either: (i) a C1-esterase inhibitor concentrate, or (ii) lanadelumab.

**Treatment criteria:**

- Must be treated by a clinical immunologist or a specialist allergist.

For the purposes of administering this restriction, an adequate response is a reduction of the baseline number of acute attacks of hereditary angioedema of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate. The details of the reduction must be documented in the patient's medical records for auditing purposes.

**garadacimab 200 mg/1.2 mL injection, 1.2 mL pen device**

15295B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | 0.00 | 30,344.99 | 25.00 | Andembry [VK] |

## GARADACIMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18321***

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Continuing preventative treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with either: (i) a C1-esterase inhibitor concentrate, or (ii) lanadelumab.

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

For the purposes of administering this restriction, an adequate response is a reduction of the baseline number of acute attacks of hereditary angioedema of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate. The details of the reduction must be documented in the patient's medical records for auditing purposes.

**garadacimab 200 mg/1.2 mL injection, 1.2 mL pen device**

15305M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 30,344.99 | 25.00 | Andembry [VK] |

## GARADACIMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18139***

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition as routine prophylaxis for hereditary angioedema prior to 1 April 2026, **AND**

- Patient must have experienced at least 12 treated acute attacks of hereditary angioedema within the 6 month period prior to commencing treatment for this condition; **OR**
- Patient must have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema immediately prior to receiving non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have received PBS-subsidised treatment with lanadelumab as routine prophylaxis for hereditary angioedema immediately prior to receiving non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have received non-PBS-subsidised treatment with garadacimab via the VANGUARD open-label extension study as routine prophylaxis for hereditary angioedema, **AND**
- The treatment must not be used in combination with either: (i) a C1-esterase inhibitor concentrate, or (ii) lanadelumab.

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

For the purposes of administering this restriction, acute attacks of hereditary angioedema are those of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate

The baseline measurement of the number of treated acute attacks of hereditary angioedema within the 6 months prior to initiating non-PBS-subsidised treatment must be provided at the time of submitting this application.

For the purposes of administering this restriction, an adequate response is a reduction of the baseline number of acute attacks of hereditary angioedema of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate. The details of the reduction must be documented in the patient's medical records for auditing purposes.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

### garadacimab 200 mg/1.2 mL injection, 1.2 mL pen device

15332Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 30,344.99 | 25.00 | Andembry [VK] |

## GARADACIMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18454***

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Initial 1: New patient (commencing with no previous treatment with C1-INH for routine prophylaxis)

**Clinical criteria:**

- Patient must have experienced at least 12 treated acute attacks of hereditary angioedema within the 6 month period prior to commencing treatment with this drug, **AND**
- Patient must not have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema at the time of application, **AND**
- The treatment must not be used in combination with either: (i) a C1-esterase inhibitor concentrate, or (ii) lanadelumab.

**Treatment criteria:**

- Must be treated by a clinical immunologist or a specialist allergist.

For the purposes of administering this restriction, acute attacks of hereditary angioedema are those of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate

The baseline measurement of the number of treated acute attacks of hereditary angioedema within the 6 months prior to initiating treatment must be provided at the time of submitting this application.

**Authority Required**

***18484***

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Initial 2: New patient (commencing from National Blood Authority-funded C1-INH)

**Clinical criteria:**

- Patient must have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema immediately prior to receiving this drug, **AND**
- The treatment must not be used in combination with either: (i) a C1-esterase inhibitor concentrate, or (ii) lanadelumab.

**Treatment criteria:**

- Must be treated by a clinical immunologist or a specialist allergist.

**Authority Required**

***18320***

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Initial 3: New patient (transitioning from PBS-subsidised lanadelumab)

**Clinical criteria:**

- Patient must have been receiving lanadelumab through the PBS as routine prophylaxis for hereditary angioedema immediately prior to receiving this drug, **AND**
- The treatment must not be used in combination with either: (i) a C1-esterase inhibitor concentrate, or (ii) lanadelumab.

**Treatment criteria:**

- Must be treated by a clinical immunologist or a specialist allergist.

### garadacimab 200 mg/1.2 mL injection, 1.2 mL pen device

15317E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 0 | 0.00 | *60,580.62 | 25.00 | Andembry [VK] |

## ICATIBANT

**Authority Required**

***7273***

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency, **AND**
- Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema, **AND**
- The condition must be assessed by a clinical immunologist; **OR**
- The condition must be assessed by a respiratory physician; **OR**
- The condition must be assessed by a specialist allergist; **OR**
- The condition must be assessed by a general physician experienced in the management of patients with hereditary angioedema.

The name of the specialist consulted must be provided at the time of application for initial supply.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

Increased maximum quantities will be limited to 12 injections per authority prescription.

**Note** Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au)

**Authority Required**

***7274***

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Increased maximum quantities will be limited to 12 injections per authority prescription.

**Note** Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au)

### icatibant 30 mg/3 mL injection, 3 mL syringe

1976B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 369.25 | 25.00 | [a] Cipla Icatibant [LR] | [a] Fyzant [JU] |
| | | | | | [a] Icatibant Lupin [GQ] | |

## LANADELUMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18498***

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Initial 1: New patient (commencing with no previous treatment with C1-INH for routine prophylaxis)

**Clinical criteria:**

- Patient must have experienced at least 12 treated acute attacks of hereditary angioedema within the 6 month period prior to commencing treatment with this drug, **AND**
- Patient must not have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema at the time of application, **AND**
- The treatment must not be used in combination with either: (i) a C1-esterase inhibitor concentrate, or (ii) garadacimab.

**Treatment criteria:**

- Must be treated by a clinical immunologist or a specialist allergist.

**Population criteria:**

- Patient must be aged 12 years or older.

For the purposes of administering this restriction, acute attacks of hereditary angioedema are those of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate

The baseline measurement of the number of treated acute attacks of hereditary angioedema within the 6 months prior to initiating treatment must be provided at the time of submitting this application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18140***

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Initial 2: New patient (commencing from National Blood Authority-funded C1-INH)

**Clinical criteria:**

- Patient must have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema immediately prior to receiving lanadelumab, **AND**
- The treatment must not be used in combination with either: (i) a C1-esterase inhibitor concentrate, or (ii) garadacimab.

**Treatment criteria:**

- Must be treated by a clinical immunologist or a specialist allergist.

**Population criteria:**

- Patient must be aged 12 years or older.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18424***

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Initial 3: New patient (transitioning from PBS-subsidised garadacimab)

**Clinical criteria:**

- Patient must have been receiving garadacimab through the PBS as routine prophylaxis for hereditary angioedema immediately prior to receiving this drug, **AND**
- The treatment must not be used in combination with either: (i) a C1-esterase inhibitor concentrate, or (ii) garadacimab.

**Treatment criteria:**

- Must be treated by a clinical immunologist or a specialist allergist.

**Population criteria:**

- Patient must be aged 12 years or older.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18239***

Chronic treatment of hereditary angioedema Types 1 or 2

Treatment Phase: Continuing preventative treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with either: (i) a C1-esterase inhibitor concentrate, or (ii) garadacimab.

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be aged 12 years or older.

Patients who have successfully transitioned to a lower dosing frequency should be reviewed every 6 months to ensure they continue to demonstrate a sustained response

For the purposes of administering this restriction, an adequate response is a reduction of the baseline number of acute attacks of hereditary angioedema of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate. The details of the reduction must be documented in the patient's medical records for auditing purposes.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### lanadelumab 300 mg/2 mL injection, 2 mL syringe

12790E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 18,772.46 | 25.00 | Takhzyro [TK] |

# CARDIOVASCULAR SYSTEM

## CARDIAC THERAPY

### CARDIAC GLYCOSIDES

#### *Digitalis glycosides*

### DIGOXIN

**Restricted benefit**

***15956***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### digoxin 50 microgram/mL oral liquid, 60 mL

3164M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | 0.00 | *43.64 | 25.00 | Lanoxin [AS] |

NP

### digoxin 62.5 microgram tablet, 200

2605D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 18.10 | 19.64 | [a] Sigmaxin-PG [LN] | |
| | | [B]2.39 | 20.49 | 19.64 | [a] Lanoxin-PG [AS] | |

NP

**digoxin 250 microgram tablet, 100**

| 1322N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 18.10 | 19.64 | a | Sigmaxin [LN] | |
| | | | [B]2.39 | 20.49 | 19.64 | a | Lanoxin [AS] | |

## ANTIARRHYTHMICS, CLASS I AND III

### *Antiarrhythmics, class Ia*

## DISOPYRAMIDE

**Note** Pharmaceutical benefits that have the form disopyramide 100 mg capsule in a pack size of 84 can be substituted for a pack size of 100 in the case of a shortage.

**Restricted benefit**

***15956***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**disopyramide 100 mg capsule, 100**

| 2923W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 26.46 | 25.00 | a | Rythmodan [PB] |

**disopyramide 100 mg capsule, 100**

| 15521X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 83.72 | 25.00 | a | Rythmodan (Japan) [OJ] |

**disopyramide 100 mg capsule, 84**

| 13280Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1.19047619 | 5 | 0.00 | *85.96 | 25.00 | a | Rythmodan (UK) [YO] |

### *Antiarrhythmics, class Ib*

## LIDOCAINE

**Restricted benefit**

***15956***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**lidocaine hydrochloride 10% (500 mg/5 mL) injection, 10 x 5 mL ampoules**

| 2876J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 35.79 | 25.00 | Xylocard 500 [AS] |

### *Antiarrhythmics, class Ic*

## FLECAINIDE

**Caution** Flecainide acetate should be avoided in patients with poor cardiac function.

**Restricted benefit**

***15965***

Serious supra-ventricular cardiac arrhythmias

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

***15966***

Serious ventricular cardiac arrhythmias

**Clinical criteria:**

- The treatment must be initiated in a hospital.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**flecainide acetate 50 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1088G NP | 1 | 5 | 0.00 | 26.27 | 25.00 | [a] APO-Flecainide [TX] | [a] Flecainide Sandoz [SZ] |
| | | | | | | [a] Flecatab [AF] | |
| | | | [B]4.86 | 31.13 | 25.00 | [a] Tambocor [IL] | |

**flecainide acetate 100 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1090J NP | 1 | 5 | 0.00 | 29.13 | 25.00 | [a] APO-Flecainide [TX] | [a] Flecainide Sandoz [SZ] |
| | | | | | | [a] Flecatab [AF] | |
| | | | [B]5.26 | 34.39 | 25.00 | [a] Tambocor [IL] | |

### *Antiarrhythmics, class III*

## AMIODARONE

**Note** This drug has been reported to cause frequent and potentially serious toxicity.
**Note** Regular monitoring of hepatic and thyroid function is recommended.

**Restricted benefit**
***15967***
Severe cardiac arrhythmias
**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**amiodarone hydrochloride 100 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2344J NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] Aratac 100 [AF] | [a] Cordarone X 100 [SW] |

**amiodarone hydrochloride 200 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2343H NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] Amdarone [XT] | [a] Amiodarone Sandoz [SZ] |
| | | | | | | [a] Aratac 200 [AF] | [a] Cordarone X 200 [SW] |

## SOTALOL

**Restricted benefit**
***15967***
Severe cardiac arrhythmias
**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**sotalol hydrochloride 80 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8398B NP | 1 | 5 | 0.00 | 18.09 | 19.63 | [a] APX-Sotalol [TY] | [a] Cardol [AF] |
| | | | | | | [a] Solavert [RF] | [a] Sotalol Sandoz [SZ] |
| | | | | | | [a] SOTALOL-WGR [WG] | |
| | | | [B]4.50 | 22.59 | 19.63 | [a] Sotacor [RW] | |

**sotalol hydrochloride 160 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2043M NP | 1 | 5 | 0.00 | 21.07 | 22.61 | [a] APX-Sotalol [TY] | [a] Cardol [AF] |
| | | | | | | [a] Solavert [RF] | [a] Sotalol Sandoz [SZ] |
| | | | | | | [a] SOTALOL-WGR [WG] | |
| | | | [B]4.84 | 25.91 | 22.61 | [a] Sotacor [RW] | |

## CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES

### *Adrenergic and dopaminergic agents*

## ADRENALINE (EPINEPHRINE)

**Note** Pharmaceutical benefits that have the form adrenaline 1 mg/mL ampoules for injection in a pack size of 10 can be substituted for a pack size of 5 in the case of a shortage.

**adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

| 1016L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 21.78 | 23.32 | Link Medical Products Pty Ltd [LM] |

**adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

| 5004J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 21.78 | 23.32 | Link Medical Products Pty Ltd [LM] |

## ADRENALINE (EPINEPHRINE)

**Caution** Adrenaline products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

**Note** The adrenaline devices should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No applications for repeats will be authorised.

**Authority Required**

***4909***

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority Required**

***8734***

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

**Authority Required**

***18922***

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

**adrenaline (epinephrine) 500 microgram/0.3 mL injection, 0.3 mL pen device**

| 12655C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *156.52 | 25.00 | Anapen 500 [XT] |

## ADRENALINE (EPINEPHRINE)

**Caution** Adrenaline products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

**Note** The adrenaline devices should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No applications for repeats will be authorised.

**Authority Required**

***18798***

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

**Population criteria:**

- Patient must be aged 4 years or older
- Patient must weigh 15 kg or more.

The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority Required**

***18795***

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

**Population criteria:**

- Patient must be aged 4 years or older
- Patient must weigh 15 kg or more.

**Authority Required**

***18924***

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

**Population criteria:**

- Patient must be aged 4 years or older
- Patient must weigh 15 kg or more.

### Adrenaline (epinephrine) 1 mg/actuation nasal spray, 2 x 1 actuation

| 15414G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 171.25 | 25.00 | neffy [CS] |

### Adrenaline (epinephrine) 2 mg/actuation nasal spray, 2 x 1 actuation

| 15404R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 171.25 | 25.00 | neffy [CS] |

## ADRENALINE (EPINEPHRINE)

**Caution** Adrenaline products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

**Note** The adrenaline devices should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au).

**Note** Pharmaceutical benefits that have the form adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device and pharmaceutical benefits that have the form adrenaline (epinephrine) 150 microgram/0.15 mL injection, 0.15 mL pen device are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No applications for repeats will be authorised.

**Authority Required**

***4909***

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority Required**

***8734***

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

**Authority Required**

***18922***

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

**adrenaline (epinephrine) 150 microgram/0.15 mL injection, 0.15 mL pen device**

| 15359J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *156.52 | 25.00 | [a] Jext Jnr [KF] |

**adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device**

| 8697R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *156.52 | 25.00 | [a] Adrenaline Jr Viatris [AF]<br>[a] EpiPen Jr. [AL] | [a] Anapen Junior 150 [XT] |

## ADRENALINE (EPINEPHRINE)

**Caution** Adrenaline products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

**Note** The adrenaline devices should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au).

**Note** Pharmaceutical benefits that have the form adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device (Adrenaline Viatris, Anapen 300 and EpiPen) and pharmaceutical benefits that have the form adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device (Jext) are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No applications for repeats will be authorised.

**Authority Required**

***4909***

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority Required**

***8734***

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

**Authority Required**

***18922***

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

**adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device**

| 8698T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *156.52 | 25.00 | [a] Adrenaline Viatris [AF] | [a] Anapen 300 [XT] |

| 8698T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] EpiPen [AL] | |

**adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device**

| 15355E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *156.52 | 25.00 | [a] Jext [KF] |

## VASODILATORS USED IN CARDIAC DISEASES

### *Organic nitrates*

### GLYCERYL TRINITRATE

**glyceryl trinitrate 5 mg/24 hours patch, 30**

| 1515R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 30.10 | 25.00 | Transiderm-Nitro 25 [SZ] |

**glyceryl trinitrate 10 mg/24 hours patch, 30**

| 1516T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 34.99 | 25.00 | Transiderm-Nitro 50 [SZ] |

### GLYCERYL TRINITRATE

**Note** The spray should not be inhaled.

**glyceryl trinitrate 400 microgram/actuation spray, 200 actuations**

| 8171C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 26.62 | 25.00 | Nitrolingual Pumpspray [SW] |

### GLYCERYL TRINITRATE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**glyceryl trinitrate 5 mg/24 hours patch, 30**

| 13490B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *45.84 | 25.00 | Transiderm-Nitro 25 [SZ] |

**glyceryl trinitrate 10 mg/24 hours patch, 30**

| 13580R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *55.62 | 25.00 | Transiderm-Nitro 50 [SZ] |

### GLYCERYL TRINITRATE

**Note** The spray should not be inhaled.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**glyceryl trinitrate 400 microgram/actuation spray, 200 actuations**

| 13549D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *38.88 | 25.00 | Nitrolingual Pumpspray [SW] |

### ISOSORBIDE DINITRATE

**isosorbide dinitrate 5 mg sublingual tablet, 100**

| 2588F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *21.84 | 23.38 | Isordil Sublingual [RW] |

### ISOSORBIDE DINITRATE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**isosorbide dinitrate 5 mg sublingual tablet, 100**

| 13491C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *29.32 | 25.00 | Isordil Sublingual [RW] |

## ISOSORBIDE MONONITRATE

### isosorbide mononitrate 60 mg modified release tablet, 30

| 1558B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APO-Isosorbide Mononitrate [TX] | [a] Duride [AF] |
| | | | | | | [a] ISOBIDE MR [RF] | [a] ISOSORBIDE MR-WGR [WG] |
| | | | [B]3.19 | 21.29 | 19.64 | [a] Imdur Durule [IX] | |

### isosorbide mononitrate 120 mg modified release tablet, 30

| 8273K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.46 | 23.00 | [a] Monodur 120 mg [IY] | |
| | | | [B]3.27 | 24.73 | 23.00 | [a] Imdur 120 mg [IX] | |

## ISOSORBIDE MONONITRATE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### isosorbide mononitrate 60 mg modified release tablet, 30

| 13461L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] APO-Isosorbide Mononitrate [TX] | [a] Duride [AF] |
| | | | | | | [a] ISOBIDE MR [RF] | [a] ISOSORBIDE MR-WGR [WG] |
| | | | [B]6.38 | 28.22 | 23.38 | [a] Imdur Durule [IX] | |

### isosorbide mononitrate 120 mg modified release tablet, 30

| 13611J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *28.56 | 25.00 | [a] Monodur 120 mg [IY] | |
| | | | [B]6.54 | *35.10 | 25.00 | [a] Imdur 120 mg [IX] | |

## *Other vasodilators used in cardiac diseases*

## NICORANDIL

### nicorandil 10 mg tablet, 60

| 8228C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 22.78 | 24.32 | [a] APO-Nicorandil [TX] | [a] Ikotab [AF] |

### nicorandil 20 mg tablet, 60

| 8229D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 26.08 | 25.00 | [a] APO-Nicorandil [TX] | [a] Ikotab [AF] |

## NICORANDIL

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### nicorandil 10 mg tablet, 60

| 13550E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *31.20 | 25.00 | [a] APO-Nicorandil [TX] | [a] Ikotab [AF] |

### nicorandil 20 mg tablet, 60

| 13551F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *37.80 | 25.00 | [a] APO-Nicorandil [TX] | [a] Ikotab [AF] |

## PERHEXILINE

**Note** Regular monitoring of drug serum levels is recommended.

**Authority Required (STREAMLINED)**

***16111***

Angina

**Clinical criteria:**

- The condition must not be responding to other therapy.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**perhexiline maleate 100 mg tablet, 100**

| 1822X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 54.61 | 25.00 | Pexsig [AS] |

## VERICIGUAT

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***13561***
Chronic heart failure
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated.

**vericiguat 2.5 mg tablet, 28**

| 13178N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 141.22 | 25.00 | Verquvo [BN] |

**vericiguat 5 mg tablet, 28**

| 13189E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 141.22 | 25.00 | Verquvo [BN] |

**vericiguat 10 mg tablet, 28**

| 13192H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 141.22 | 25.00 | Verquvo [BN] |

## VERICIGUAT

**Note** The date of the decompensation event and date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**
***16562***
Chronic heart failure
Treatment Phase: Initial treatment
**Treatment criteria:**

- Must be treated by a cardiologist; **OR**
- Must be treated by an authorised prescriber (medical practitioner, nurse practitioner) who has been directed to prescribe this medicine by a cardiologist.

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than 45%, **AND**
- The condition must be stabilised following a decompensation event that required at least one of: (i) hospitalisation in the past 6 months, (ii) intravenous diuretic therapy in the past three months, **AND**
- Patient must not have clinical signs of fluid overload, **AND**
- Patient must not have received intravenous treatment for fluid overload in the previous 24 hours, **AND**
- Patient must not have a systolic blood pressure less than 100 mmHg, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**

- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated.

**vericiguat 2.5 mg tablet, 28**

| 13181R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 141.22 | 25.00 | Verquvo [BN] |

**vericiguat 5 mg tablet, 28**

| 13186B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 141.22 | 25.00 | Verquvo [BN] |

**vericiguat 10 mg tablet, 28**

| 13193J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 141.22 | 25.00 | Verquvo [BN] |

## OTHER CARDIAC PREPARATIONS

### *Other cardiac preparations*

### IVABRADINE

**Authority Required (STREAMLINED)**

***4979***

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II or III, **AND**
- Patient must be in sinus rhythm, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%, **AND**
- Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.

Resting heart rate should be measured by ECG or echocardiography, after 5 minutes rest.

The ECG or echocardiography, result must be documented in the patient's medical records when treatment is initiated.

**ivabradine 5 mg tablet, 56**

| 10012Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 46.72 | 25.00 | [a] APO-Ivabradine [TX] | [a] Coralan [SE] |
| | | | | | | [a] IVABRADINE-WGR [WG] | |

**ivabradine 7.5 mg tablet, 56**

| 2960T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 46.72 | 25.00 | [a] APO-Ivabradine [TX] | [a] Coralan [SE] |

### IVABRADINE

**Authority Required (STREAMLINED)**

***18079***

Chronic heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II or III, **AND**
- Patient must be in sinus rhythm, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%, **AND**
- Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.

Resting heart rate should be measured by ECG or echocardiography, after 5 minutes rest.

The ECG or echocardiography, result must be documented in the patient's medical records when treatment is initiated.

**ivabradine 5 mg tablet, 56**

| 15270Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *79.08 | 25.00 | [a] APO-Ivabradine [TX] | [a] Coralan [SE] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 15270Q | | | | | | [a] IVABRADINE-WGR [WG] | |

**ivabradine 7.5 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 15241E NP | 2 | 5 | 0.00 | *79.08 | 25.00 | [a] APO-Ivabradine [TX] | [a] Coralan [SE] |

## MAVACAMTEN

**Caution** The patient's condition should be assessed prior to receiving treatment and closely monitored throughout the treatment period.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18625***

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: First continuing treatment (until at least 6 months on optimal dose is achieved)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must be titrating mavacamten treatment until optimal dose is achieved; **OR**
- Patient must be continuing mavacamten treatment to reach at least 6 months on the optimal dose prior to assessing the response.

**Treatment criteria:**

- Must be treated by a cardiologist; **OR**
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

The assessment of response must be conducted after at least 6 months on optimal dose to determine the patient's eligibility for maintenance treatment. Where an assessment is not undertaken, the patient will not be eligible for ongoing treatment. This treatment phase listing intends to provide up to 36 weeks of treatment in 3 treatment courses.

For the purposes of this restriction, an adequate response to treatment is defined as: an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**mavacamten 10 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14137C | 1 | 2 | 0.00 | 2,336.27 | 25.00 | Camzyos [BQ] |

**mavacamten 15 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14139E | 1 | 2 | 0.00 | 2,336.27 | 25.00 | Camzyos [BQ] |

## MAVACAMTEN

**Caution** The patient's condition should be assessed prior to receiving treatment and closely monitored throughout the treatment period.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16425***

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: Subsequent continuing treatment - Maintenance treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-

dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**

- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must have demonstrated a response after at least 6 months on the optimal dose of mavacamten treatment defined as an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.

**Treatment criteria:**

- Must be treated by a cardiologist; **OR**
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

**mavacamten 2.5 mg capsule, 28**

| 14123H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 2,336.27 | 25.00 | Camzyos [BQ] |

**mavacamten 5 mg capsule, 28**

| 14113T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 2,336.27 | 25.00 | Camzyos [BQ] |

**mavacamten 10 mg capsule, 28**

| 14138D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 2,336.27 | 25.00 | Camzyos [BQ] |

**mavacamten 15 mg capsule, 28**

| 14124J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 2,336.27 | 25.00 | Camzyos [BQ] |

## MAVACAMTEN

**Caution** The patient's condition should be assessed prior to receiving treatment and closely monitored throughout the treatment period.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18253***

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: Initial treatment (covering the first 12 weeks of therapy)

**Clinical criteria:**

- Patient must have confirmed left ventricular hypertrophy due to hypertrophic cardiomyopathy, **AND**
- Patient must have maximal end-diastolic left ventricular wall thickness which is at least one of either: (i) no less than 15 mm; (ii) no less than 13 mm if patient has familial hypertrophic cardiomyopathy (at least one first degree relative with a diagnosis of hypertrophic cardiomyopathy), **AND**
- Patient must have confirmed peak left ventricular outflow tract (LVOT) gradient of no less than 50 mm Hg which is measured either: (i) at rest; (ii) after provocation with at least one of (a) Valsalva manoeuvre, (b) exercise, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 55%, **AND**
- Patient must have had prior treatments with each of a (i) beta-blocker and (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must be symptomatic with NYHA classes II or III.

**Treatment criteria:**

- Must be treated by a cardiologist; **OR**
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include all the following:

(1) Details of the proposed prescription; and

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(3) The details of the echocardiogram and/ or cardiac magnetic resonance imaging (MRI) report confirming the diagnosis of hypertrophic cardiomyopathy (HCM). State all the following:

(a) the date, unique identifying number/code or provider number of the report;

(b) the left ventricular wall thickness in millimetres (mm).

(4) The details of a genotyping test report if the patient had been tested. State all the following:
(a) the date, unique identifying number/code or provider number of the report;
(b) if a gene has been identified that is associated with HCM;
(c) if any first-degree family relative has a confirmed diagnosis of HCM.
(5) The details of the LVOT gradient report. State all the following:
(a) the date, unique identifying number/code or provider number of the report;
(b) the measured LVOT gradient;
(c) how the LVOT gradient was measured (rest, Valsalva manoeuvre or exercise).
(6) NYHA status.
(7) The current beta-blocker or non-dihydropyridine calcium channel blocker (either diltiazem or verapamil only) therapy if applicable.
(8) Prior beta-blocker or non-dihydropyridine calcium channel blocker trials, including:
(a) if the patient is currently taking beta-blocker therapy, state the previous therapy with non-dihydropyridine calcium channel blocker that was trialled confirming that it was not effective;
(b) if the patient is currently taking non-dihydropyridine calcium channel blocker therapy, state the previous therapy with beta-blocker that was trialled confirming that it was not effective;
(c) if there is contraindication or intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information, specify the details.
All results and reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***18625***

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: First continuing treatment (until at least 6 months on optimal dose is achieved)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must be titrating mavacamten treatment until optimal dose is achieved; **OR**
- Patient must be continuing mavacamten treatment to reach at least 6 months on the optimal dose prior to assessing the response.

**Treatment criteria:**

- Must be treated by a cardiologist; **OR**
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

The assessment of response must be conducted after at least 6 months on optimal dose to determine the patient's eligibility for maintenance treatment. Where an assessment is not undertaken, the patient will not be eligible for ongoing treatment. This treatment phase listing intends to provide up to 36 weeks of treatment in 3 treatment courses.

For the purposes of this restriction, an adequate response to treatment is defined as: an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**mavacamten 2.5 mg capsule, 28**

14135Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 2,336.27 | 25.00 | Camzyos [BQ] |

**mavacamten 5 mg capsule, 28**

14117B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 2,336.27 | 25.00 | Camzyos [BQ] |

# ANTIHYPERTENSIVES

## ANTIADRENERGIC AGENTS, CENTRALLY ACTING

### *Methyldopa*

### METHYLDOPA

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***16273***

Hypertension

**Population criteria:**

- Patient must be pregnant.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

**methyldopa 250 mg tablet, 100**

| 1629R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 5 | 0.00 | 22.89 | 24.43 | [a] Hydopa [AF] | |
| | | | [B]3.47 | 26.36 | 24.43 | [a] Aldomet [AS] | |

### *Imidazoline receptor agonists*

### CLONIDINE

**clonidine hydrochloride 100 microgram tablet, 100**

| 3145M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 26.32 | 25.00 | [a] APO-Clonidine [TX] | [a] Catapres 100 [IX] |
| | | | | | | [a] Clonidine Lupin [GQ] | |

**clonidine hydrochloride 150 microgram tablet, 100**

| 3141H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 32.31 | 25.00 | Catapres [IX] |

### CLONIDINE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**clonidine hydrochloride 100 microgram tablet, 100**

| 13578P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *38.28 | 25.00 | [a] APO-Clonidine [TX] | [a] Catapres 100 [IX] |
| | | | | | | [a] Clonidine Lupin [GQ] | |

**clonidine hydrochloride 150 microgram tablet, 100**

| 13548C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *50.26 | 25.00 | Catapres [IX] |

### MOXONIDINE

**Restricted benefit**

***4944***

Hypertension

**Clinical criteria:**

- Patient must be receiving concurrent antihypertensive therapy.

**moxonidine 200 microgram tablet, 30**

| 9019Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Moxonidine [TX] | [a] ARX-MOXONIDINE [TY] |
| | | | | | | [a] Moxonidine GH [GQ] | [a] Moxonidine GX [SZ] |
| | | | | | | [a] Moxonidine Viatris [AL] | [a] MOXONIDINE-WGR [WG] |
| | | | | | | [a] Moxotens [RF] | [a] Physiotens [GO] |

**moxonidine 400 microgram tablet, 30**

| 9020R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.64 | 22.18 | [a] APO-Moxonidine [TX] | [a] ARX-MOXONIDINE [TY] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9020R | | | | | | [a] Moxonidine GH [GQ] | [a] Moxonidine GX [SZ] |
| | | | | | | [a] Moxonidine Viatris [AL] | [a] MOXONIDINE-WGR [WG] |
| | | | | | | [a] Moxotens [RF] | [a] Physiotens [GO] |

### MOXONIDINE

**Restricted benefit**

***14289***

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving concurrent antihypertensive therapy.

**moxonidine 200 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13579Q | | | | | | | |
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Moxonidine [TX] | [a] ARX-MOXONIDINE [TY] |
| | | | | | | [a] Moxonidine GH [GQ] | [a] Moxonidine GX [SZ] |
| | | | | | | [a] Moxonidine Viatris [AL] | [a] MOXONIDINE-WGR [WG] |
| | | | | | | [a] Moxotens [RF] | [a] Physiotens [GO] |

**moxonidine 400 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13552G | | | | | | | |
| NP | 2 | 5 | 0.00 | *26.92 | 25.00 | [a] APO-Moxonidine [TX] | [a] ARX-MOXONIDINE [TY] |
| | | | | | | [a] Moxonidine GH [GQ] | [a] Moxonidine GX [SZ] |
| | | | | | | [a] Moxonidine Viatris [AL] | [a] MOXONIDINE-WGR [WG] |
| | | | | | | [a] Moxotens [RF] | [a] Physiotens [GO] |

## ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING

### *Alpha-adrenoreceptor antagonists*

### PRAZOSIN

**prazosin 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1479W | | | | | | | |
| NP | 1 | 5 | 0.00 | 18.44 | 19.98 | [a] APO-Prazosin [TX] | [a] Minipress [PF] |

**prazosin 2 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1480X | | | | | | | |
| NP | 1 | 5 | 0.00 | 20.07 | 21.61 | [a] APO-Prazosin [TX] | [a] Minipress [PF] |

**prazosin 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1478T | | | | | | | |
| NP | 1 | 5 | 0.00 | 24.60 | 25.00 | [a] APO-Prazosin [TX] | [a] Minipress [PF] |

### PRAZOSIN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**prazosin 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13553H | | | | | | | |
| NP | 2 | 5 | 0.00 | *22.52 | 24.06 | [a] APO-Prazosin [TX] | [a] Minipress [PF] |

**prazosin 2 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13400G | | | | | | | |
| NP | 2 | 5 | 0.00 | *25.78 | 25.00 | [a] APO-Prazosin [TX] | [a] Minipress [PF] |

**prazosin 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13367M | | | | | | | |
| NP | 2 | 5 | 0.00 | *34.84 | 25.00 | [a] APO-Prazosin [TX] | [a] Minipress [PF] |

## ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON

### *Pyrimidine derivatives*

### MINOXIDIL

**Restricted benefit**

***5177***

Severe refractory hypertension

**Clinical criteria:**

- The treatment must be initiated by a consultant physician.

**minoxidil 10 mg tablet, 100**

| 2313R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 44.36 | 25.00 | Loniten [PF] |

### MINOXIDIL

**Restricted benefit**

***14994***

Severe refractory hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be initiated by a consultant physician.

**minoxidil 10 mg tablet, 100**

| 14041B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *74.36 | 25.00 | Loniten [PF] |

## DIURETICS

### LOW-CEILING DIURETICS, THIAZIDES

#### *Thiazides, plain*

### HYDROCHLOROTHIAZIDE

**hydrochlorothiazide 25 mg tablet, 100**

| 1484D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 22.27 | 23.81 | Dithiazide [FF] |

### HYDROCHLOROTHIAZIDE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**hydrochlorothiazide 25 mg tablet, 100**

| 13409R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *30.18 | 25.00 | Dithiazide [FF] |

### LOW-CEILING DIURETICS, EXCL. THIAZIDES

#### *Sulfonamides, plain*

### CHLORTALIDONE

**chlortalidone 25 mg tablet, 50**

| 1585K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *22.16 | 23.70 | Hygroton 25 [GH] |

### CHLORTALIDONE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**chlortalidone 25 mg tablet, 50**

| 13500M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 1 | 0.00 | *29.96 | 25.00 | Hygroton 25 [GH] |

### INDAPAMIDE

**indapamide hemihydrate 1.5 mg modified release tablet, 90**

| 8532C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 19.67 | 21.21 | [a] APO-Indapamide SR [TX] | [a] Natrilix SR [SE] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8532C | | | | | | [a] Odaplix SR [AF] | |

**indapamide hemihydrate 2.5 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2436F NP | 1 | 1 | 0.00 | 18.60 | 20.14 | [a] Dapa-Tabs [AF] | [a] Insig [RW] |

## INDAPAMIDE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**indapamide hemihydrate 1.5 mg modified release tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13475F NP | 2 | 1 | 0.00 | *24.98 | 25.00 | [a] APO-Indapamide SR [TX] | [a] Natrilix SR [SE] |
| | | | | | | [a] Odaplix SR [AF] | |

**indapamide hemihydrate 2.5 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13378D NP | 2 | 1 | 0.00 | *22.84 | 24.38 | [a] Dapa-Tabs [AF] | [a] Insig [RW] |

# HIGH-CEILING DIURETICS

## *Sulfonamides, plain*

## FUROSEMIDE

**furosemide 10 mg/mL oral liquid, 30 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2411X NP | ‡1 | 3 | 0.00 | 41.27 | 25.00 | Lasix [SW] |

**furosemide 20 mg/2 mL injection, 5 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2413B NP | 1 | 0 | 0.00 | 17.47 | 19.01 | Lasix [SW] |

**furosemide 40 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2412Y NP | 1 | 1 | 0.00 | 17.10 | 18.64 | [a] APO-Frusemide [TX] | [a] Frusax [ZS] |
| | | | | | | [a] FUROSEMIDE-WGR [WG] | [a] Uremide [AF] |
| | | | [B]0.99 | 18.09 | 18.64 | [a] Frusemix [TY] | |

**furosemide 500 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2415D NP | 1 | 3 | 0.00 | 23.87 | 25.00 | Urex-Forte [RW] |

## FUROSEMIDE

**Note** For item codes 2414C and 1810G, pharmaceutical benefits that have the form tablet 20 mg are equivalent for the purposes of substitution.

**furosemide 20 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1810G NP | 2 | 1 | 0.00 | *19.84 | 21.38 | [a] Frusemix-M [TY] | [a] UREMIDE 20 [AF] |

**furosemide 20 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2414C NP | 1 | 1 | 0.00 | 19.60 | 21.14 | [a] APO-Frusemide [TX] | [a] FUROSEMIDE-WGR [WG] |
| | | | | | | [a] UREMIDE 20 [AF] | |
| | | | [B]1.01 | 20.61 | 21.14 | [a] Frusemix-M [TY] | |

## FUROSEMIDE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**furosemide 10 mg/mL oral liquid, 30 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13504R NP | ‡2 | 3 | 0.00 | *68.18 | 25.00 | Lasix [SW] |

**furosemide 40 mg tablet, 100**

| 13472C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *19.84 | 21.38 | [a] APO-Frusemide [TX] | [a] Frusax [ZS] |
| | | | | | | [a] FUROSEMIDE-WGR [WG] | [a] Uremide [AF] |
| | | | [B]1.98 | 21.82 | 21.38 | [a] Frusemix [TY] | |

**furosemide 500 mg tablet, 50**

| 13474E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *33.38 | 25.00 | Urex-Forte [RW] |

## FUROSEMIDE

**Note** Pharmaceutical benefits that have the form furosemide 20 mg tablet, 50 and pharmaceutical benefits that have the form furosemide 20 mg tablet, 100 are equivalent for the purposes of substitution.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**furosemide 20 mg tablet, 100**

| 13473D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *24.84 | 25.00 | [a] APO-Frusemide [TX] | [a] FUROSEMIDE-WGR [WG] |
| | | | | | | [a] UREMIDE 20 [AF] | |
| | | | [B]2.02 | 26.86 | 25.00 | [a] Frusemix-M [TY] | |

**furosemide 20 mg tablet, 50**

| 13501N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 1 | 0.00 | *25.32 | 25.00 | [a] Frusemix-M [TY] | [a] UREMIDE 20 [AF] |

## ALDOSTERONE ANTAGONISTS AND OTHER POTASSIUM-SPARING AGENTS

### *Aldosterone antagonists*

## EPLERENONE

**Caution** Serum electrolytes should be checked regularly

**Authority Required (STREAMLINED)**

***18461***

Chronic heart failure

**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker: (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, **AND**
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated.

**eplerenone 25 mg tablet, 30**

| 8879H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 53.77 | 25.00 | [a] APO-Eplerenone [TX] | [a] Eplerenone Viatris [AL] |
| | | | | | | [a] ESPLER [RW] | [a] Inpler [AF] |
| | | | | | | [a] Inspra [GO] | |

**eplerenone 50 mg tablet, 30**

| 8880J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 53.77 | 25.00 | [a] APO-Eplerenone [TX] | [a] ESPLER [RW] |
| | | | | | | [a] Inpler [AF] | [a] Inspra [GO] |

## EPLERENONE

**Caution** Serum electrolytes should be checked regularly

**Authority Required (STREAMLINED)**

***18337***

Chronic heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker: (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, **AND**
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated.

**eplerenone 25 mg tablet, 30**

| 13590G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *93.18 | 25.00 | [a] APO-Eplerenone [TX] | [a] Eplerenone Viatris [AL] |
| | | | | | | [a] ESPLER [RW] | [a] Inpler [AF] |
| | | | | | | [a] Inspra [GO] | |

**eplerenone 50 mg tablet, 30**

| 13379E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *93.18 | 25.00 | [a] APO-Eplerenone [TX] | [a] ESPLER [RW] |
| | | | | | | [a] Inpler [AF] | [a] Inspra [GO] |

## FINERENONE

**Caution** Serum electrolytes should be checked regularly

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***14097***

Chronic kidney disease with Type 2 diabetes

**Clinical criteria:**

- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must not have known significant non-diabetic renal disease, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of 25 mL/min/1.73 $m^2$ or greater, prior to initiating treatment with this drug, **AND**
- Patient must have a urinary albumin-to-creatinine ratio of 200 mg/g (22.6 mg/mmol) or greater, prior to initiating treatment with this drug, **AND**
- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug, **AND**
- The treatment must be in combination with an SGLT2i unless medically contraindicated or intolerant, **AND**
- Patient must not be receiving treatment with another selective nonsteroidal mineralocorticoid receptor antagonist, a renin inhibitor or a potassium-sparing diuretic, **AND**
- Patient must not have established heart failure with reduced ejection fraction with an indication for treatment with a mineralocorticoid receptor antagonist.

**finerenone 10 mg tablet, 28**

| 13335W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 83.28 | 25.00 | Kerendia [BN] |

**finerenone 20 mg tablet, 28**

| 13316W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 83.28 | 25.00 | Kerendia [BN] |

## SPIRONOLACTONE

**Caution** Serum electrolytes should be checked regularly

**Caution** Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

**spironolactone 25 mg tablet, 100**

| 2339D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] Spironolactone Viatris 25 [AL] | |
| | | | [B]4.42 | 22.52 | 19.64 | [a] Spiractin 25 [AF] | |
| | | | [B]7.33 | 25.43 | 19.64 | [a] Aldactone [PF] | |

**spironolactone 100 mg tablet, 100**

| 2340E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 28.72 | 25.00 | [a] Spironolactone Viatris 100 [AL] | |
| | | | [B]4.37 | 33.09 | 25.00 | [a] Spiractin 100 [AF] | |
| | | | [B]7.28 | 36.00 | 25.00 | [a] Aldactone [PF] | |

## SPIRONOLACTONE

**Caution** Serum electrolytes should be checked regularly

**Caution** Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**spironolactone 25 mg tablet, 100**

| 13503Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] Spironolactone Viatris 25 [AL] | |
| | | | [B]8.84 | *30.68 | 23.38 | [a] Spiractin 25 [AF] | |
| | | | [B]14.66 | *36.50 | 23.38 | [a] Aldactone [PF] | |

**spironolactone 100 mg tablet, 100**

| 14042C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *43.08 | 25.00 | [a] Spironolactone Viatris 100 [AL] | |
| | | | [B]8.74 | *51.82 | 25.00 | [a] Spiractin 100 [AF] | |
| | | | [B]14.56 | *57.64 | 25.00 | [a] Aldactone [PF] | |

# DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION

## *Low-ceiling diuretics and potassium-sparing agents*

## AMILORIDE + HYDROCHLOROTHIAZIDE

**Caution** Serum electrolytes should be checked regularly.

**amiloride hydrochloride dihydrate 5 mg + hydrochlorothiazide 50 mg tablet, 50**

| 1486F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *24.28 | 25.00 | Moduretic [AS] |

## AMILORIDE + HYDROCHLOROTHIAZIDE

**Caution** Serum electrolytes should be checked regularly.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**amiloride hydrochloride dihydrate 5 mg + hydrochlorothiazide 50 mg tablet, 50**

| 13410T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 1 | 0.00 | *34.20 | 25.00 | Moduretic [AS] |

# OTHER DIURETICS

## *Vasopressin antagonists*

## TOLVAPTAN

**Caution** Tolvaptan has been associated with idiosyncratic hepatic toxicity. Liver function monitoring is required.

**Authority Required**

***10250***

Autosomal dominant polycystic kidney disease (ADPKD)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a nephrologist.

**Clinical criteria:**

- Patient must have an estimated glomerular filtration rate (eGFR) between 30 and 89 mL/min 1.73 $m^2$ at the initiation of treatment with this drug for this condition, **AND**
- Patient must have or have had rapidly progressing disease at the time of initiation of this drug for this condition.

Rapidly progressing disease is defined as either of the following:

A decline in eGFR of greater than or equal to 5 mL/min/1.73 $m^2$ within one year;
OR
An average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 $m^2$ per year over a five year period.

**tolvaptan 15 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12460T | 1 | 5 | 0.00 | 282.47 | 25.00 | Jinarc [OS] |

**tolvaptan 15 mg tablet [28] (&) tolvaptan 45 mg tablet [28], 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11602P | 1 | 5 | 0.00 | 555.57 | 25.00 | [a] Jinarc [OS] | [a] Tolvaptan Lupin [GQ] |

**tolvaptan 30 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12461W | 1 | 5 | 0.00 | 282.47 | 25.00 | Jinarc [OS] |

**tolvaptan 30 mg tablet [28] (&) tolvaptan 60 mg tablet [28], 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11597J | 1 | 5 | 0.00 | 555.57 | 25.00 | [a] Jinarc [OS] | [a] Tolvaptan Lupin [GQ] |

**tolvaptan 30 mg tablet [28] (&) tolvaptan 90 mg tablet [28], 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11588X | 1 | 5 | 0.00 | 555.57 | 25.00 | [a] Jinarc [OS] | [a] Tolvaptan Lupin [GQ] |

## TOLVAPTAN

**Caution** Tolvaptan has been associated with idiosyncratic hepatic toxicity. Liver function monitoring is required.

**Authority Required (STREAMLINED)**

***8288***

Autosomal dominant polycystic kidney disease (ADPKD)
Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a nephrologist or in consultation with a nephrologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have end-stage renal disease defined as an estimated glomerular filtration rate (eGFR) of less than 15 mL/min/1.73$m^2$, **AND**
- Patient must not have had a kidney transplant.

**tolvaptan 15 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12457P | 1 | 5 | 0.00 | 282.47 | 25.00 | Jinarc [OS] |

**tolvaptan 15 mg tablet [28] (&) tolvaptan 45 mg tablet [28], 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11600M | 1 | 5 | 0.00 | 555.57 | 25.00 | [a] Jinarc [OS] | [a] Tolvaptan Lupin [GQ] |

**tolvaptan 30 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12462X | 1 | 5 | 0.00 | 282.47 | 25.00 | Jinarc [OS] |

**tolvaptan 30 mg tablet [28] (&) tolvaptan 60 mg tablet [28], 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11593E | 1 | 5 | 0.00 | 555.57 | 25.00 | [a] Jinarc [OS] | [a] Tolvaptan Lupin [GQ] |

**tolvaptan 30 mg tablet [28] (&) tolvaptan 90 mg tablet [28], 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11596H | 1 | 5 | 0.00 | 555.57 | 25.00 | [a] Jinarc [OS] | [a] Tolvaptan Lupin [GQ] |

# PERIPHERAL VASODILATORS

## PERIPHERAL VASODILATORS

### *Other peripheral vasodilators*

## PHENOXYBENZAMINE

**Restricted benefit**

***16499***

Phaeochromocytoma

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**Restricted benefit**

***16567***

Neurogenic urinary retention

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**phenoxybenzamine hydrochloride 10 mg capsule, 30**

| 1166J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *659.16 | 25.00 | Amdipharm Mercury (Australia) Pty Limited [GH] |

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

| 1862B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 731.38 | 25.00 | Dibenyline [GH] |

# BETA BLOCKING AGENTS

## BETA BLOCKING AGENTS

### *Beta blocking agents, non-selective*

### PROPRANOLOL

**propranolol hydrochloride 10 mg tablet, 100**

| 2565B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.66 | 19.20 | [a] APO-Propranolol [TX] | [a] PROPRANOLOL-WGR [WG] |
| | | | [B]2.79 | 20.45 | 19.20 | [a] Deralin 10 [AF] | |
| | | | [B]8.12 | 25.78 | 19.20 | [a] Inderal [IX] | |

**propranolol hydrochloride 40 mg tablet, 100**

| 2566C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.91 | 19.45 | [a] APO-Propranolol [TX] | [a] PROPRANOLOL-WGR [WG] |
| | | | [B]2.80 | 20.71 | 19.45 | [a] Deralin 40 [AF] | |
| | | | [B]8.13 | 26.04 | 19.45 | [a] Inderal [IX] | |

### PROPRANOLOL

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**propranolol hydrochloride 10 mg tablet, 100**

| 13386M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *20.96 | 22.50 | [a] APO-Propranolol [TX] | [a] PROPRANOLOL-WGR [WG] |
| | | | [B]5.58 | *26.54 | 22.50 | [a] Deralin 10 [AF] | |
| | | | [B]16.24 | *37.20 | 22.50 | [a] Inderal [IX] | |

**propranolol hydrochloride 40 mg tablet, 100**

| 13542R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.46 | 23.00 | [a] APO-Propranolol [TX] | [a] PROPRANOLOL-WGR [WG] |
| | | | [B]5.60 | *27.06 | 23.00 | [a] Deralin 40 [AF] | |
| | | | [B]16.26 | *37.72 | 23.00 | [a] Inderal [IX] | |

### *Beta blocking agents, selective*

### ATENOLOL

**atenolol 50 mg tablet, 30**

| 1081X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APX-Atenolol [TY] | [a] Atenolol GH [GQ] |
| | | | | | | [a] Atenolol Sandoz [SZ] | [a] ATENOLOL-WGR [WG] |
| | | | | | | [a] Blooms The Chemist Atenolol [BG] | [a] Noten [AF] |
| | | | | | | [a] Tensig [RW] | |
| | | | [B]12.93 | 30.03 | 18.64 | [a] Tenormin [IX] | |

## ATENOLOL

**Restricted benefit**

***4076***

For a patient who is unable to take a solid dose form of atenolol.

**atenolol 50 mg/10 mL oral liquid, 300 mL**

| 2243C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 50.37 | 25.00 | Atenolol-AFT [AE] |

## ATENOLOL

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**atenolol 50 mg tablet, 30**

| 13540P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APX-Atenolol [TY] | [a] Atenolol GH [GQ] |
| | | | | | | [a] Atenolol Sandoz [SZ] | [a] ATENOLOL-WGR [WG] |
| | | | | | | [a] Blooms The Chemist Atenolol [BG] | [a] Noten [AF] |
| | | | | | | [a] Tensig [RW] | |
| | | | [B]25.86 | 45.70 | 21.38 | [a] Tenormin [IX] | |

## ATENOLOL

**Restricted benefit**

***14305***

For a patient who is unable to take a solid dose form of atenolol.

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**atenolol 50 mg/10 mL oral liquid, 300 mL**

| 13600T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *86.38 | 25.00 | Atenolol-AFT [AE] |

## BISOPROLOL

**Restricted benefit**

***5324***

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**bisoprolol fumarate 2.5 mg tablet, 28**

| 8604W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Bisoprolol [TX] | [a] Bicard 2.5 [RW] |
| | | | | | | [a] Bisoprolol generichealth [GQ] | [a] Bisoprolol Sandoz [SZ] |
| | | | | | | [a] BISOPROLOL-WGR [WG] | [a] Bispro 2.5 [AF] |
| | | | [B]5.27 | 23.87 | 20.14 | [a] Bicor [AL] | |

**bisoprolol fumarate 5 mg tablet, 28**

| 8605X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Bisoprolol [TX] | [a] Bicard 5 [RW] |
| | | | | | | [a] Bisoprolol generichealth [GQ] | [a] Bisoprolol Sandoz [SZ] |
| | | | | | | [a] BISOPROLOL-WGR [WG] | [a] Bispro 5 [AF] |
| | | | [B]4.18 | 22.78 | 20.14 | [a] Bicor [AL] | |

**bisoprolol fumarate 10 mg tablet, 28**

| 8606Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.00 | 20.54 | [a] APO-Bisoprolol [TX] | [a] Bicard 10 [RW] |
| | | | | | | [a] Bisoprolol generichealth [GQ] | [a] Bisoprolol Sandoz [SZ] |
| | | | | | | [a] BISOPROLOL-WGR [WG] | [a] Bispro 10 [AF] |
| | | | [B]3.69 | 22.69 | 20.54 | [a] Bicor [AL] | |

## BISOPROLOL

**Restricted benefit**

***14251***

Moderate to severe heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

### bisoprolol fumarate 2.5 mg tablet, 28

| 13419G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Bisoprolol [TX] | [a] Bicard 2.5 [RW] |
| | | | | | | [a] Bisoprolol generichealth [GQ] | [a] Bisoprolol Sandoz [SZ] |
| | | | | | | [a] BISOPROLOL-WGR [WG] | [a] Bispro 2.5 [AF] |
| | | | [B]10.54 | 33.38 | 24.38 | [a] Bicor [AL] | |

### bisoprolol fumarate 5 mg tablet, 28

| 13443M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Bisoprolol [TX] | [a] Bicard 5 [RW] |
| | | | | | | [a] Bisoprolol generichealth [GQ] | [a] Bisoprolol Sandoz [SZ] |
| | | | | | | [a] BISOPROLOL-WGR [WG] | [a] Bispro 5 [AF] |
| | | | [B]8.36 | 31.20 | 24.38 | [a] Bicor [AL] | |

### bisoprolol fumarate 10 mg tablet, 28

| 13444N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *23.64 | 25.00 | [a] APO-Bisoprolol [TX] | [a] Bicard 10 [RW] |
| | | | | | | [a] Bisoprolol generichealth [GQ] | [a] Bisoprolol Sandoz [SZ] |
| | | | | | | [a] BISOPROLOL-WGR [WG] | [a] Bispro 10 [AF] |
| | | | [B]7.38 | 31.02 | 25.00 | [a] Bicor [AL] | |

## METOPROLOL SUCCINATE

**Restricted benefit**

***5324***

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

### METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15

| 8732N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 18.60 | 20.14 | [a] Metrol-XL 23.75 [RW] | [a] Minax XL [AF] |
| | | | | | | [a] Topreloc-XL [CR] | |

### METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30

| 8733P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 32.03 | 25.00 | [a] Metrol-XL 47.5 [RW] | [a] Minax XL [AF] |
| | | | | | | [a] Topreloc-XL [CR] | [a] Toprol-XL 47.5 [AP] |

### METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30

| 8734Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 36.44 | 25.00 | [a] Metrol-XL 95 [RW] | [a] Minax XL [AF] |
| | | | | | | [a] Topreloc-XL [CR] | [a] Toprol-XL 95 [AP] |

### METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30

| 8735R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 41.97 | 25.00 | [a] Metrol-XL 190 [RW] | [a] Minax XL [AF] |
| | | | | | | [a] Topreloc-XL [CR] | [a] Toprol-XL 190 [AP] |

## METOPROLOL SUCCINATE

**Restricted benefit**

***14251***

Moderate to severe heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

### METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30

| 13543T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *49.70 | 25.00 | [a] Metrol-XL 47.5 [RW] | [a] Minax XL [AF] |
| | | | | | | [a] Topreloc-XL [CR] | [a] Toprol-XL 47.5 [AP] |

### METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30

| 13544W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *58.52 | 25.00 | [a] Metrol-XL 95 [RW] | [a] Minax XL [AF] |
| | | | | | | [a] Topreloc-XL [CR] | [a] Toprol-XL 95 [AP] |

### METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30

| 13420H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *69.58 | 25.00 | [a] Metrol-XL 190 [RW] | [a] Minax XL [AF] |
| | | | | | | [a] Topreloc-XL [CR] | [a] Toprol-XL 190 [AP] |

## METOPROLOL TARTRATE

### METOPROLOL TARTRATE Tablet 50 mg, 100

| 1324Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 0.00 | 17.10 | 18.64 | Mistrom [ZS] | [a] APO-Metoprolol [TX] |
| | | | | | | [a] Metoprolol Sandoz [SZ] | [a] METOPROLOL-WGR [WG] |
| | | | | | | [a] Metrol 50 [RW] | [a] Minax 50 [AF] |
| | | | [B]12.64 | 29.74 | 18.64 | [a] Betaloc [AP] | |

### METOPROLOL TARTRATE Tablet 100 mg, 60

| 1325R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 0.00 | 17.36 | 18.90 | Mistrom [ZS] | [a] APO-Metoprolol [TX] |
| | | | | | | [a] Metoprolol Sandoz [SZ] | [a] METOPROLOL-WGR [WG] |
| | | | | | | [a] Metrol 100 [RW] | [a] Minax 100 [AF] |
| | | | [B]12.63 | 29.99 | 18.90 | [a] Betaloc [AP] | |

## METOPROLOL TARTRATE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### METOPROLOL TARTRATE Tablet 50 mg, 100

| 13598Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 0.00 | *19.84 | 21.38 | Mistrom [ZS] | [a] APO-Metoprolol [TX] |
| | | | | | | [a] Metoprolol Sandoz [SZ] | [a] METOPROLOL-WGR [WG] |
| | | | | | | [a] Metrol 50 [RW] | [a] Minax 50 [AF] |
| | | | [B]25.28 | 45.12 | 21.38 | [a] Betaloc [AP] | |

### METOPROLOL TARTRATE Tablet 100 mg, 60

| 13541Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 0.00 | *20.36 | 21.90 | Mistrom [ZS] | [a] APO-Metoprolol [TX] |
| | | | | | | [a] Metoprolol Sandoz [SZ] | [a] METOPROLOL-WGR [WG] |
| | | | | | | [a] Metrol 100 [RW] | [a] Minax 100 [AF] |
| | | | [B]25.26 | 45.62 | 21.90 | [a] Betaloc [AP] | |

## NEBIVOLOL

**Restricted benefit**

***5324***

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**nebivolol 1.25 mg tablet, 28**

| 9316H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *32.28 | 25.00 | [a] APO-Nebivolol [TX] | [a] Nebilet [FK] |
| | | | | | | [a] Nebivolol Lupin [GQ] | [a] Nebivolol Sandoz [SZ] |
| | | | | | | [a] Nebivolol Viatris [AL] | [a] NEBIVOLOL-WGR [WG] |
| | | | | | | [a] Nepiten [AF] | |

**nebivolol 5 mg tablet, 28**

| 9311C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 36.72 | 25.00 | [a] APO-Nebivolol [TX] | [a] Nebaloc [CR] |
| | | | | | | [a] Nebilet [FK] | [a] Nebivolol Lupin [GQ] |
| | | | | | | [a] Nebivolol Sandoz [SZ] | [a] Nebivolol Viatris [AL] |
| | | | | | | [a] NEBIVOLOL-WGR [WG] | [a] Nepiten [AF] |

**nebivolol 10 mg tablet, 28**

| 9312D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 39.64 | 25.00 | [a] APO-Nebivolol [TX] | [a] Nebaloc [CR] |
| | | | | | | [a] Nebilet [FK] | [a] Nebivolol Lupin [GQ] |
| | | | | | | [a] Nebivolol Sandoz [SZ] | [a] NEBIVOLOL-WGR [WG] |
| | | | | | | [a] Nepiten [AF] | |

## NEBIVOLOL

**Restricted benefit**

***14251***

Moderate to severe heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**nebivolol 1.25 mg tablet, 28**

| 13568D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *50.20 | 25.00 | [a] APO-Nebivolol [TX] | [a] Nebilet [FK] |
| | | | | | | [a] Nebivolol Lupin [GQ] | [a] Nebivolol Sandoz [SZ] |
| | | | | | | [a] Nebivolol Viatris [AL] | [a] NEBIVOLOL-WGR [WG] |
| | | | | | | [a] Nepiten [AF] | |

**nebivolol 5 mg tablet, 28**

| 13510C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *59.08 | 25.00 | [a] APO-Nebivolol [TX] | [a] Nebaloc [CR] |
| | | | | | | [a] Nebilet [FK] | [a] Nebivolol Lupin [GQ] |
| | | | | | | [a] Nebivolol Sandoz [SZ] | [a] Nebivolol Viatris [AL] |
| | | | | | | [a] NEBIVOLOL-WGR [WG] | [a] Nepiten [AF] |

**nebivolol 10 mg tablet, 28**

| 13441K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *64.92 | 25.00 | [a] APO-Nebivolol [TX] | [a] Nebaloc [CR] |
| | | | | | | [a] Nebilet [FK] | [a] Nebivolol Lupin [GQ] |
| | | | | | | [a] Nebivolol Sandoz [SZ] | [a] NEBIVOLOL-WGR [WG] |
| | | | | | | [a] Nepiten [AF] | |

### *Alpha and beta blocking agents*

## CARVEDILOL

**Restricted benefit**

***5324***

Moderate to severe heart failure

**Clinical criteria:**

- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**Restricted benefit**

***5394***

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

**carvedilol 3.125 mg tablet, 30**

| 8255L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 17.93 | 19.47 | [a] APO-Carvedilol [TX] | [a] Carvidol [RF] |
| | | | | | | [a] Vedilol 3.125 [RW] | [a] Volirop 3.125 [ZS] |

**carvedilol 6.25 mg tablet, 60**

| 8256M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Carvedilol [TX] | [a] Carvedilol Sandoz [SZ] |
| | | | | | | [a] CARVEDILOL-WGR [WG] | [a] Carvidol [RF] |
| | | | | | | [a] Dicarz [AF] | [a] Dilatrend 6.25 [PB] |
| | | | | | | [a] Vedilol 6.25 [RW] | [a] Volirop 6.25 [ZS] |

**carvedilol 12.5 mg tablet, 60**

| 8257N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Carvedilol [TX] | [a] Carvedilol Sandoz [SZ] |
| | | | | | | [a] CARVEDILOL-WGR [WG] | [a] Carvidol [RF] |
| | | | | | | [a] Dicarz [AF] | [a] Dilatrend 12.5 [PB] |
| | | | | | | [a] Vedilol 12.5 [RW] | [a] Volirop 12.5 [ZS] |

**carvedilol 25 mg tablet, 60**

| 8258P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.39 | 20.93 | [a] APO-Carvedilol [TX] | [a] Carvedilol Sandoz [SZ] |
| | | | | | | [a] CARVEDILOL-WGR [WG] | [a] Carvidol [RF] |
| | | | | | | [a] Dicarz [AF] | [a] Dilatrend 25 [PB] |
| | | | | | | [a] Vedilol 25 [RW] | [a] Volirop 25 [ZS] |

## CARVEDILOL

**Restricted benefit**

***14251***

Moderate to severe heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

**Restricted benefit**

***14270***

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**carvedilol 6.25 mg tablet, 60**

| 13417E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Carvedilol [TX] | [a] Carvedilol Sandoz [SZ] |
| | | | | | | [a] CARVEDILOL-WGR [WG] | [a] Carvidol [RF] |
| | | | | | | [a] Dicarz [AF] | [a] Dilatrend 6.25 [PB] |
| | | | | | | [a] Vedilol 6.25 [RW] | [a] Volirop 6.25 [ZS] |

**carvedilol 12.5 mg tablet, 60**

| 13418F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Carvedilol [TX] | [a] Carvedilol Sandoz [SZ] |
| | | | | | | [a] CARVEDILOL-WGR [WG] | [a] Carvidol [RF] |
| | | | | | | [a] Dicarz [AF] | [a] Dilatrend 12.5 [PB] |
| | | | | | | [a] Vedilol 12.5 [RW] | [a] Volirop 12.5 [ZS] |

**carvedilol 25 mg tablet, 60**

| 13387N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.42 | 25.00 | [a] APO-Carvedilol [TX] | [a] Carvedilol Sandoz [SZ] |
| | | | | | | [a] CARVEDILOL-WGR [WG] | [a] Carvidol [RF] |
| | | | | | | [a] Dicarz [AF] | [a] Dilatrend 25 [PB] |
| | | | | | | [a] Vedilol 25 [RW] | [a] Volirop 25 [ZS] |

## LABETALOL

**Restricted benefit**

***16261***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

**labetalol hydrochloride 100 mg tablet, 100**

| 1566K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 5 | 0.00 | 31.50 | 25.00 | Presolol 100 [AF] |

## LABETALOL

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**labetalol hydrochloride 100 mg tablet, 100**

| 13887X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *48.64 | 25.00 | Presolol 100 [AF] |

# CALCIUM CHANNEL BLOCKERS

## SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS

### *Dihydropyridine derivatives*

## AMLODIPINE

**amlodipine 5 mg tablet, 30**

| 2751T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] Amlo 5 [RW] | [a] Amlodipine GH [GQ] |
| | | | | | | [a] Amlodipine Sandoz [SZ] | [a] AMLODIPINE-WGR [WG] |
| | | | | | | [a] APO-Amlodipine [TX] | [a] APX-AMLODIPINE [TW] |
| | | | | | | [a] Blooms Amlodipine [BG] | [a] Nordip [AF] |
| | | | | | | [a] Pharmacor Amlodipine [CR] | |
| | | | [B]10.73 | 27.83 | 18.64 | [a] Norvasc [AS] | |

**amlodipine 10 mg tablet, 30**

| 2752W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] Amlo 10 [RW] | [a] Amlodipine GH [GQ] |
| | | | | | | [a] Amlodipine Sandoz [SZ] | [a] AMLODIPINE-WGR [WG] |
| | | | | | | [a] APO-Amlodipine [TX] | [a] APX-AMLODIPINE [TW] |
| | | | | | | [a] Blooms Amlodipine [BG] | [a] Nordip [AF] |
| | | | | | | [a] Pharmacor Amlodipine [CR] | |
| | | | [B]10.74 | 27.84 | 18.64 | [a] Norvasc [AS] | |

## AMLODIPINE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**amlodipine 5 mg tablet, 30**

| 13532F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Amlo 5 [RW] | [a] Amlodipine GH [GQ] |
| | | | | | | [a] Amlodipine Sandoz [SZ] | [a] AMLODIPINE-WGR [WG] |
| | | | | | | [a] APO-Amlodipine [TX] | [a] APX-AMLODIPINE [TW] |
| | | | | | | [a] Blooms Amlodipine [BG] | [a] Nordip [AF] |
| | | | | | | [a] Pharmacor Amlodipine [CR] | |
| | | | [B]21.46 | 41.30 | 21.38 | [a] Norvasc [AS] | |

**amlodipine 10 mg tablet, 30**

| 13562T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Amlo 10 [RW] | [a] Amlodipine GH [GQ] |

| 13562T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Amlodipine Sandoz [SZ] | [a] AMLODIPINE-WGR [WG] |
| | | | | | | [a] APO-Amlodipine [TX] | [a] APX-AMLODIPINE [TW] |
| | | | | | | [a] Blooms Amlodipine [BG] | [a] Nordip [AF] |
| | | | | | | [a] Pharmacor Amlodipine [CR] | |
| | | | [B]21.48 | 41.32 | 21.38 | [a] Norvasc [AS] | |

## FELODIPINE

### felodipine 2.5 mg modified release tablet, 30

| 2361G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.71 | 19.25 | [a] Felodil XR 2.5 [XT] | [a] Felodur ER 2.5 mg [IY] |
| | | | [B]3.74 | 21.45 | 19.25 | [a] Plendil ER [IX] | |

### felodipine 5 mg modified release tablet, 30

| 2366M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.35 | 19.89 | [a] Felodil XR 5 [RW] | [a] Felodur ER 5 mg [IY] |
| | | | [B]3.69 | 22.04 | 19.89 | [a] Plendil ER [IX] | |

### felodipine 10 mg modified release tablet, 30

| 2367N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.44 | 22.98 | [a] Felodil XR 10 [RW] | [a] Felodur ER 10 mg [IY] |
| | | | [B]3.64 | 25.08 | 22.98 | [a] Plendil ER [IX] | |

## FELODIPINE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### felodipine 2.5 mg modified release tablet, 30

| 13377C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.06 | 22.60 | [a] Felodil XR 2.5 [XT] | [a] Felodur ER 2.5 mg [IY] |
| | | | [B]7.48 | *28.54 | 22.60 | [a] Plendil ER [IX] | |

### felodipine 5 mg modified release tablet, 30

| 13561R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.34 | 23.88 | [a] Felodil XR 5 [RW] | [a] Felodur ER 5 mg [IY] |
| | | | [B]7.38 | *29.72 | 23.88 | [a] Plendil ER [IX] | |

### felodipine 10 mg modified release tablet, 30

| 13531E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *28.52 | 25.00 | [a] Felodil XR 10 [RW] | [a] Felodur ER 10 mg [IY] |
| | | | [B]7.28 | *35.80 | 25.00 | [a] Plendil ER [IX] | |

## LERCANIDIPINE

### lercanidipine hydrochloride 10 mg tablet, 28

| 8534E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] ARX-LERCANIDIPINE [TX] | [a] Lercan [RW] |
| | | | | | | [a] LERCANIDIPINE-WGR [WG] | [a] Zircol 10 [AL] |
| | | | [B]3.27 | 20.37 | 18.64 | [a] Zanidip [GO] | |

### lercanidipine hydrochloride 20 mg tablet, 28

| 8679T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] ARX-LERCANIDIPINE [TX] | [a] Lercan [RW] |
| | | | | | | [a] LERCANIDIPINE-WGR [WG] | [a] Zircol 20 [AL] |
| | | | [B]3.30 | 21.40 | 19.64 | [a] Zanidip [GO] | |

## LERCANIDIPINE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**lercanidipine hydrochloride 10 mg tablet, 28**

| 13411W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] ARX-LERCANIDIPINE [TX] | [a] Lercan [RW] |
| | | | | | | [a] LERCANIDIPINE-WGR [WG] | [a] Zircol 10 [AL] |
| | | | [B]6.54 | 26.38 | 21.38 | [a] Zanidip [GO] | |

**lercanidipine hydrochloride 20 mg tablet, 28**

| 13412X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] ARX-LERCANIDIPINE [TX] | [a] Lercan [RW] |
| | | | | | | [a] LERCANIDIPINE-WGR [WG] | [a] Zircol 20 [AL] |
| | | | [B]6.60 | 28.44 | 23.38 | [a] Zanidip [GO] | |

## NIFEDIPINE

**nifedipine 30 mg modified release tablet, 30**

| 1906H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.05 | 22.59 | APO-Nifedipine XR [TX] |

**nifedipine 60 mg modified release tablet, 30**

| 1907J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 22.76 | 24.30 | APO-Nifedipine XR [TX] |

## NIFEDIPINE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**nifedipine 30 mg modified release tablet, 30**

| 13502P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *27.74 | 25.00 | APO-Nifedipine XR [TX] |

**nifedipine 60 mg modified release tablet, 30**

| 13376B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *31.16 | 25.00 | APO-Nifedipine XR [TX] |

# SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS

### *Phenylalkylamine derivatives*

## VERAPAMIL

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

**verapamil hydrochloride 80 mg tablet, 100**

| 1250T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.78 | 22.32 | [a] Anpec 80 [AF] | |
| | | | [B]3.01 | 23.79 | 22.32 | [a] Isoptin [GO] | |

**verapamil hydrochloride 180 mg modified release tablet, 30**

| 2208F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.57 | 21.11 | [a] Cordilox 180 SR [GT] | |
| | | | [B]3.41 | 22.98 | 21.11 | [a] Isoptin 180 SR [GO] | |

**verapamil hydrochloride 240 mg modified release tablet, 30**

| 1241H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.28 | 22.82 | [a] Cordilox SR [GT] | |
| | | | [B]3.40 | 24.68 | 22.82 | [a] Isoptin SR [GO] | |

## VERAPAMIL

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**verapamil hydrochloride 80 mg tablet, 100**

| 13530D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *27.20 | 25.00 | [a] Anpec 80 [AF] | |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13530D | | | [B]6.02 | *33.22 | 25.00 | [a] Isoptin [GO] | |

**verapamil hydrochloride 180 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13434C | | | | | | | |
| NP | 2 | 5 | 0.00 | *24.78 | 25.00 | [a] Cordilox 180 SR [GT] | |
| | | | [B]6.82 | *31.60 | 25.00 | [a] Isoptin 180 SR [GO] | |

**verapamil hydrochloride 240 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13408Q | | | | | | | |
| NP | 2 | 5 | 0.00 | *28.20 | 25.00 | [a] Cordilox SR [GT] | |
| | | | [B]6.80 | *35.00 | 25.00 | [a] Isoptin SR [GO] | |

### *Benzothiazepine derivatives*

## DILTIAZEM

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

**diltiazem hydrochloride 60 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1335G | | | | | | | |
| NP | 1 | 5 | 0.00 | 22.08 | 23.62 | [a] Vasocardol [AV] | |
| | | | [B]1.84 | 23.92 | 23.62 | [a] Cardizem [SW] | |

**diltiazem hydrochloride 180 mg modified release capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1312C | | | | | | | |
| NP | 1 | 5 | 0.00 | 19.99 | 21.53 | [a] Diltiazem Sandoz CD [SZ] | [a] Vasocardol CD [AV] |
| | | | [B]1.59 | 21.58 | 21.53 | [a] Cardizem CD [SW] | |

**diltiazem hydrochloride 240 mg modified release capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1313D | | | | | | | |
| NP | 1 | 5 | 0.00 | 21.96 | 23.50 | [a] Diltiazem Sandoz CD [SZ] | [a] Vasocardol CD [AV] |
| | | | [B]1.60 | 23.56 | 23.50 | [a] Cardizem CD [SW] | |

**diltiazem hydrochloride 360 mg modified release capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8480H | | | | | | | |
| NP | 1 | 5 | 0.00 | 25.92 | 25.00 | [a] Diltiazem Sandoz CD [SZ] | [a] Vasocardol CD [AV] |

## DILTIAZEM

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**diltiazem hydrochloride 60 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14479C | | | | | | | |
| NP | 2 | 5 | 0.00 | *29.80 | 25.00 | [a] Vasocardol [AV] | |
| | | | [B]3.68 | *33.48 | 25.00 | [a] Cardizem [SW] | |

**diltiazem hydrochloride 180 mg modified release capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14564M | | | | | | | |
| NP | 2 | 5 | 0.00 | *25.62 | 25.00 | [a] Diltiazem Sandoz CD [SZ] | [a] Vasocardol CD [AV] |
| | | | [B]3.18 | *28.80 | 25.00 | [a] Cardizem CD [SW] | |

**diltiazem hydrochloride 240 mg modified release capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14508N | | | | | | | |
| NP | 2 | 5 | 0.00 | *29.56 | 25.00 | [a] Diltiazem Sandoz CD [SZ] | [a] Vasocardol CD [AV] |
| | | | [B]3.20 | *32.76 | 25.00 | [a] Cardizem CD [SW] | |

**diltiazem hydrochloride 360 mg modified release capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14565N | | | | | | | |
| NP | 2 | 5 | 0.00 | *37.48 | 25.00 | [a] Diltiazem Sandoz CD [SZ] | [a] Vasocardol CD [AV] |

# AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

## ACE INHIBITORS, PLAIN

### *ACE inhibitors, plain*

## CAPTOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

***4996***

Patients unable to take a solid dose form of an ACE inhibitor.

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### captopril 5 mg/mL oral liquid, 95 mL

| 8760C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 107.31 | 25.00 | Capoten [RW] |

## ENALAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### enalapril maleate 5 mg tablet, 30

| 1370D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] Acetec [AL] | [a] APO-Enalapril [TX] |
| | | | | | | [a] Enalapril Sandoz [SZ] | [a] ENALAPRIL-WGR [WG] |
| | | | | | | [a] Malean [RW] | |

### enalapril maleate 10 mg tablet, 30

| 1368B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.97 | 19.51 | [a] Acetec [AL] | [a] APO-Enalapril [TX] |
| | | | | | | [a] Enalapril Sandoz [SZ] | [a] ENALAPRIL-WGR [WG] |
| | | | | | | [a] Malean [RW] | |
| | | | [B]10.00 | 27.97 | 19.51 | [a] Renitec [AF] | |

### enalapril maleate 20 mg tablet, 30

| 1369C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.25 | 19.79 | [a] Acetec [AL] | [a] APO-Enalapril [TX] |
| | | | | | | [a] Enalapril Sandoz [SZ] | [a] ENALAPRIL-WGR [WG] |
| | | | | | | [a] Malean [RW] | |
| | | | [B]10.00 | 28.25 | 19.79 | [a] Renitec 20 [AF] | |

## ENALAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### enalapril maleate 5 mg tablet, 30

| 13369P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Acetec [AL] | [a] APO-Enalapril [TX] |
| | | | | | | [a] Enalapril Sandoz [SZ] | [a] ENALAPRIL-WGR [WG] |
| | | | | | | [a] Malean [RW] | |

### enalapril maleate 10 mg tablet, 30

| 13465Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.58 | 23.12 | [a] Acetec [AL] | [a] APO-Enalapril [TX] |
| | | | | | | [a] Enalapril Sandoz [SZ] | [a] ENALAPRIL-WGR [WG] |
| | | | | | | [a] Malean [RW] | |
| | | | [B]20.00 | 41.58 | 23.12 | [a] Renitec [AF] | |

### enalapril maleate 20 mg tablet, 30

| 13401H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.14 | 23.68 | [a] Acetec [AL] | [a] APO-Enalapril [TX] |
| | | | | | | [a] Enalapril Sandoz [SZ] | [a] ENALAPRIL-WGR [WG] |
| | | | | | | [a] Malean [RW] | |
| | | | [B]20.00 | 42.14 | 23.68 | [a] Renitec 20 [AF] | |

## FOSINOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### fosinopril sodium 10 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1182F | | | | | | | |
| NP | 1 | 5 | 0.00 | 18.78 | 20.32 | [a] APO-Fosinopril [TX] | [a] Monace 10 [AF] |

### fosinopril sodium 20 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1183G | | | | | | | |
| NP | 1 | 5 | 0.00 | 20.87 | 22.41 | [a] APO-Fosinopril [TX] | [a] Monace 20 [AF] |

## LISINOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### lisinopril 5 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2456G | | | | | | | |
| NP | 1 | 5 | 0.00 | 17.11 | 18.65 | [a] APO-Lisinopril [TX] | [a] Fibsol 5 [RW] |
| | | | | | | [a] Lisinopril Sandoz [SZ] | [a] LISINOPRIL-WGR [WG] |
| | | | | | | [a] Zinopril 5 [AL] | |
| | | | [B]4.56 | 21.67 | 18.65 | [a] Zestril [IX] | |

### lisinopril 10 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2457H | | | | | | | |
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APO-Lisinopril [TX] | [a] Fibsol 10 [RW] |
| | | | | | | [a] Lisinopril Sandoz [SZ] | [a] LISINOPRIL-WGR [WG] |
| | | | | | | [a] Zinopril 10 [AL] | |
| | | | [B]4.60 | 22.70 | 19.64 | [a] Zestril [IX] | |

### lisinopril 20 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2458J | | | | | | | |
| NP | 1 | 5 | 0.00 | 18.39 | 19.93 | [a] APO-Lisinopril [TX] | [a] Fibsol 20 [RW] |
| | | | | | | [a] Lisinopril Sandoz [SZ] | [a] LISINOPRIL-WGR [WG] |
| | | | | | | [a] Zinopril 20 [AL] | |
| | | | [B]4.62 | 23.01 | 19.93 | [a] Zestril [IX] | |

## LISINOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### lisinopril 5 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13583X | | | | | | | |
| NP | 2 | 5 | 0.00 | *19.86 | 21.40 | [a] APO-Lisinopril [TX] | [a] Fibsol 5 [RW] |
| | | | | | | [a] Lisinopril Sandoz [SZ] | [a] LISINOPRIL-WGR [WG] |
| | | | | | | [a] Zinopril 5 [AL] | |
| | | | [B]9.12 | 28.98 | 21.40 | [a] Zestril [IX] | |

### lisinopril 10 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13584Y | | | | | | | |
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] APO-Lisinopril [TX] | [a] Fibsol 10 [RW] |
| | | | | | | [a] Lisinopril Sandoz [SZ] | [a] LISINOPRIL-WGR [WG] |
| | | | | | | [a] Zinopril 10 [AL] | |
| | | | [B]9.20 | 31.04 | 23.38 | [a] Zestril [IX] | |

### lisinopril 20 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13402J | | | | | | | |
| NP | 2 | 5 | 0.00 | *22.42 | 23.96 | [a] APO-Lisinopril [TX] | [a] Fibsol 20 [RW] |
| | | | | | | [a] Lisinopril Sandoz [SZ] | [a] LISINOPRIL-WGR [WG] |
| | | | | | | [a] Zinopril 20 [AL] | |

| 13402J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | [B]9.24 | 31.66 | 23.96 | [a] Zestril [IX] | |

## PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

### perindopril erbumine 2 mg tablet, 30

| 3050M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Perindopril [TX] | [a] PERINDOPRIL-WGR [WG] |
| | | | | | | [a] PERISYL [AL] | |

### perindopril arginine 2.5 mg tablet, 30

| 9006B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Perindopril Arginine [TX] | [a] APX-Perindopril Arginine [XT] |
| | | | | | | [a] Perindopril Arginine Sandoz [SZ] | [a] Perindopril Arginine-WGR [WG] |
| | | | | | | [a] PREXUM 2.5 [RX] | |
| | | | [B]9.34 | 26.44 | 18.64 | [a] Coversyl 2.5mg [SE] | |

## PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 4 mg tablet and pharmaceutical benefits that have the form perindopril arginine 5 mg tablet are equivalent for the purposes of substitution.

### perindopril erbumine 4 mg tablet, 30

| 3051N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.76 | 19.30 | [a] APO-Perindopril [TX] | [a] PERINDOPRIL-WGR [WG] |
| | | | | | | [a] PERISYL [AL] | |

### perindopril arginine 5 mg tablet, 30

| 9007C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.76 | 19.30 | [a] APO-Perindopril Arginine [TX] | [a] APX-Perindopril Arginine [XT] |
| | | | | | | [a] Perindopril Arginine Sandoz [SZ] | [a] Perindopril Arginine-WGR [WG] |
| | | | | | | [a] PREXUM 5 [RX] | |
| | | | [B]9.06 | 26.82 | 19.30 | [a] Coversyl 5mg [SE] | |

## PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 8 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet are equivalent for the purposes of substitution.

### perindopril erbumine 8 mg tablet, 30

| 8704D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Perindopril [TX] | [a] PERINDOPRIL-WGR [WG] |
| | | | | | | [a] PERISYL [AL] | |

### perindopril arginine 10 mg tablet, 30

| 9008D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Perindopril Arginine [TX] | [a] APX-Perindopril Arginine [XT] |
| | | | | | | [a] Perindopril Arginine Sandoz [SZ] | [a] Perindopril Arginine-WGR [WG] |
| | | | | | | [a] PREXUM 10 [RX] | |
| | | | [B]9.39 | 27.99 | 20.14 | [a] Coversyl 10mg [SE] | |

## PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 4 mg tablet and pharmaceutical benefits that have the form perindopril arginine 5 mg tablet are equivalent for the purposes of substitution.

**Restricted benefit**

***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**perindopril erbumine 4 mg tablet, 30**

| 13371R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.16 | 22.70 | [a] APO-Perindopril [TX] | [a] PERINDOPRIL-WGR [WG] |
| | | | | | | [a] PERISYL [AL] | |

**perindopril arginine 5 mg tablet, 30**

| 13585B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.16 | 22.70 | [a] APO-Perindopril Arginine [TX] | [a] APX-Perindopril Arginine [XT] |
| | | | | | | [a] Perindopril Arginine Sandoz [SZ] | [a] Perindopril Arginine-WGR [WG] |
| | | | | | | [a] PREXUM 5 [RX] | |
| | | | [B]18.12 | 39.28 | 22.70 | [a] Coversyl 5mg [SE] | |

## PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 8 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet are equivalent for the purposes of substitution.

**Restricted benefit**

***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**perindopril erbumine 8 mg tablet, 30**

| 13372T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Perindopril [TX] | [a] PERINDOPRIL-WGR [WG] |
| | | | | | | [a] PERISYL [AL] | |

**perindopril arginine 10 mg tablet, 30**

| 13555K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Perindopril Arginine [TX] | [a] APX-Perindopril Arginine [XT] |
| | | | | | | [a] Perindopril Arginine Sandoz [SZ] | [a] Perindopril Arginine-WGR [WG] |
| | | | | | | [a] PREXUM 10 [RX] | |
| | | | [B]18.78 | 41.62 | 24.38 | [a] Coversyl 10mg [SE] | |

## PERINDOPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril erbumine 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

**Restricted benefit**

***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**perindopril erbumine 2 mg tablet, 30**

| 13404L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APO-Perindopril [TX] | [a] PERINDOPRIL-WGR [WG] |
| | | | | | | [a] PERISYL [AL] | |

**perindopril arginine 2.5 mg tablet, 30**

| 13494F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APO-Perindopril Arginine [TX] | [a] APX-Perindopril Arginine [XT] |
| | | | | | | [a] Perindopril Arginine Sandoz [SZ] | [a] Perindopril Arginine-WGR [WG] |
| | | | | | | [a] PREXUM 2.5 [RX] | |
| | | | [B]18.68 | 38.52 | 21.38 | [a] Coversyl 2.5mg [SE] | |

## QUINAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**quinapril 5 mg tablet, 30**

| 1968N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.01 | 19.55 | ACQUIN [RF] |

**quinapril 10 mg tablet, 30**

| 1969P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.31 | 19.85 | APO-Quinapril [TX] |

**quinapril 20 mg tablet, 30**

| 1970Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.18 | 20.72 | APO-Quinapril [TX] |

## RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 10 mg tablet and pharmaceutical benefits that have the form ramipril 10 mg capsule are equivalent for the purposes of substitution.

**ramipril 10 mg tablet, 30**

| 1316G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APO-Ramipril [TX] | [a] Ramipril Sandoz [SZ] |
| | | | | | | [a] RAMIPRIL TABS-WGR [WG] | [a] Ramipril Viatris [AL] |
| | | | | | | [a] Tritace [SW] | |

**ramipril 10 mg capsule, 30**

| 8470T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APO-Ramipril [TX] | [a] APX-Ramipril [TY] |
| | | | | | | [a] Prilace [RF] | [a] Ramipril Sandoz [SZ] |
| | | | | | | [a] RAMIPRIL-WGR [WG] | [a] Tritace 10 mg [SW] |
| | | | | | | [a] Tryzan Caps 10 [AF] | |

## RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg capsule are equivalent for the purposes of substitution.

**ramipril 1.25 mg tablet, 30**

| 1944H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] Prilace [RF] | [a] Ramipril Sandoz [SZ] |
| | | | | | | [a] Ramipril Viatris [AL] | [a] RAMIPRIL-WGR [WG] |

**ramipril 1.25 mg capsule, 30**

| 9120B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] Tryzan Caps 1.25 [AF] |

## RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 2.5 mg tablet and pharmaceutical benefits that have the form ramipril 2.5 mg capsule are equivalent for the purposes of substitution.

**ramipril 2.5 mg tablet, 30**

| 1945J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Ramipril [TX] | [a] Prilace [RF] |
| | | | | | | [a] Ramipril Sandoz [SZ] | [a] Ramipril Viatris [AL] |
| | | | | | | [a] RAMIPRIL-WGR [WG] | [a] Ramipril Winthrop [WA] |
| | | | | | | [a] Tritace 2.5 mg [SW] | |

**ramipril 2.5 mg capsule, 30**

| 9121C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Ramipril [TX] | [a] Tryzan Caps 2.5 [AF] |

## RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.

### ramipril 5 mg tablet, 30

| 1946K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Ramipril [TX] | [a] Prilace [RF] |
| | | | | | | [a] Ramipril Sandoz [SZ] | [a] Ramipril Viatris [AL] |
| | | | | | | [a] RAMIPRIL-WGR [WG] | [a] Ramipril Winthrop [WA] |
| | | | | | | [a] Tritace 5 mg [SW] | |

### ramipril 5 mg capsule, 30

| 9122D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Ramipril [TX] | [a] Tryzan Caps 5 [AF] |

## RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 10 mg tablet and pharmaceutical benefits that have the form ramipril 10 mg capsule are equivalent for the purposes of substitution.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### ramipril 10 mg tablet, 30

| 13368N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] APO-Ramipril [TX] | [a] Ramipril Sandoz [SZ] |
| | | | | | | [a] RAMIPRIL TABS-WGR [WG] | [a] Ramipril Viatris [AL] |
| | | | | | | [a] Tritace [SW] | |

### ramipril 10 mg capsule, 30

| 13430W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] APO-Ramipril [TX] | [a] APX-Ramipril [TY] |
| | | | | | | [a] Prilace [RF] | [a] Ramipril Sandoz [SZ] |
| | | | | | | [a] RAMIPRIL-WGR [WG] | [a] Tritace 10 mg [SW] |
| | | | | | | [a] Tryzan Caps 10 [AF] | |

## RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 2.5 mg tablet and pharmaceutical benefits that have the form ramipril 2.5 mg capsule are equivalent for the purposes of substitution.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### ramipril 2.5 mg capsule, 30

| 13405M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APO-Ramipril [TX] | [a] Tryzan Caps 2.5 [AF] |

### ramipril 2.5 mg tablet, 30

| 13466R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APO-Ramipril [TX] | [a] Prilace [RF] |
| | | | | | | [a] Ramipril Sandoz [SZ] | [a] Ramipril Viatris [AL] |
| | | | | | | [a] RAMIPRIL-WGR [WG] | [a] Ramipril Winthrop [WA] |
| | | | | | | [a] Tritace 2.5 mg [SW] | |

## RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg capsule are equivalent for the purposes of substitution.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ramipril 1.25 mg capsule, 30**

| 13431X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Tryzan Caps 1.25 [AF] |

**ramipril 1.25 mg tablet, 30**

| 13582W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Prilace [RF] | [a] Ramipril Sandoz [SZ] |
| | | | | | | [a] Ramipril Viatris [AL] | [a] RAMIPRIL-WGR [WG] |

## RAMIPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form ramipril 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ramipril 5 mg tablet, 30**

| 13526X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APO-Ramipril [TX] | [a] Prilace [RF] |
| | | | | | | [a] Ramipril Sandoz [SZ] | [a] Ramipril Viatris [AL] |
| | | | | | | [a] RAMIPRIL-WGR [WG] | [a] Ramipril Winthrop [WA] |
| | | | | | | [a] Tritace 5 mg [SW] | |

**ramipril 5 mg capsule, 30**

| 13556L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APO-Ramipril [TX] | [a] Tryzan Caps 5 [AF] |

## TRANDOLAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**trandolapril 500 microgram capsule, 28**

| 2791X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] Dolapril 0.5 [RW] | [a] Tranalpha [AF] |
| | | | | | | [a] Trandolapril Viatris [AL] | |
| | | | [B]3.27 | 20.37 | 18.64 | [a] Gopten [GO] | |

**trandolapril 1 mg capsule, 28**

| 2792Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.29 | 19.83 | [a] Dolapril 1 [RW] | [a] Tranalpha [AF] |
| | | | | | | [a] Trandolapril Viatris [AL] | |
| | | | [B]3.32 | 21.61 | 19.83 | [a] Gopten [GO] | |

**trandolapril 2 mg capsule, 28**

| 2793B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.05 | 20.59 | [a] Dolapril 2 [RW] | [a] Tranalpha [AF] |
| | | | | | | [a] Trandolapril Viatris [AL] | |
| | | | [B]3.34 | 22.39 | 20.59 | [a] Gopten [GO] | |

**trandolapril 4 mg capsule, 28**

| 8758Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 23.08 | 24.62 | [a] Dolapril 4 [RW] | [a] Gopten [GO] |
| | | | | | | [a] Tranalpha [AF] | [a] Trandolapril Viatris [AL] |

## TRANDOLAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**trandolapril 500 microgram capsule, 28**

| 13554J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Dolapril 0.5 [RW] | [a] Tranalpha [AF] |
| | | | | | | [a] Trandolapril Viatris [AL] | |
| | | | [B]6.54 | 26.38 | 21.38 | [a] Gopten [GO] | |

**trandolapril 1 mg capsule, 28**

| 13429T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.22 | 23.76 | [a] Dolapril 1 [RW] | [a] Tranalpha [AF] |
| | | | | | | [a] Trandolapril Viatris [AL] | |
| | | | [B]6.64 | 28.86 | 23.76 | [a] Gopten [GO] | |

**trandolapril 2 mg capsule, 28**

| 13403K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *23.74 | 25.00 | [a] Dolapril 2 [RW] | [a] Tranalpha [AF] |
| | | | | | | [a] Trandolapril Viatris [AL] | |
| | | | [B]6.68 | 30.42 | 25.00 | [a] Gopten [GO] | |

**trandolapril 4 mg capsule, 28**

| 13467T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *31.80 | 25.00 | [a] Dolapril 4 [RW] | [a] Gopten [GO] |
| | | | | | | [a] Tranalpha [AF] | [a] Trandolapril Viatris [AL] |

## ACE INHIBITORS, COMBINATIONS

### *ACE inhibitors and diuretics*

### ENALAPRIL + HYDROCHLOROTHIAZIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30**

| 8477E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.81 | 20.35 | [a] Enalapril/HCT Sandoz [SZ] | |
| | | | [B]6.70 | 25.51 | 20.35 | [a] Renitec Plus 20/6 [AF] | |

### ENALAPRIL + HYDROCHLOROTHIAZIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30**

| 13439H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *23.26 | 24.80 | [a] Enalapril/HCT Sandoz [SZ] | |
| | | | [B]13.40 | *36.66 | 24.80 | [a] Renitec Plus 20/6 [AF] | |

### PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30**

| 2190G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] PREXUM Combi LD 2.5/0.625 [RX] | |
| | | | [B]7.51 | 24.61 | 18.64 | [a] Coversyl Plus LD 2.5mg/0.625mg [SE] | |

### PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

**perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30**

| 8449Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APO-Perindopril/Indapamide [TX] | [a] GenRx Perindopril/ Indapamide 4/1.25 [GX] |
| | | | | | | [a] PERINDOPRIL/INDAPAMIDE-WGR 4/1.25 [WG] | [a] PERISYL COMBI 4/1.25 [AL] |

**perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30**

| 2845R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] Prexum Combi 5/1.25 [RX] | |
| | | | [B]6.84 | 24.94 | 19.64 | [a] Coversyl Plus 5mg/1.25mg [SE] | |

## PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30**

| 13413Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] PREXUM Combi LD 2.5/0.625 [RX] | |
| | | | [B]15.02 | *34.86 | 21.38 | [a] Coversyl Plus LD 2.5mg/0.625mg [SE] | |

## PERINDOPRIL + INDAPAMIDE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note** Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30**

| 13476G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] APO-Perindopril/Indapamide [TX] | [a] GenRx Perindopril/ Indapamide 4/1.25 [GX] |
| | | | | | | [a] PERINDOPRIL/INDAPAMIDE-WGR 4/1.25 [WG] | [a] PERISYL COMBI 4/1.25 [AL] |

**perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30**

| 13506W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] Prexum Combi 5/1.25 [RX] | |
| | | | [B]13.68 | *35.52 | 23.38 | [a] Coversyl Plus 5mg/1.25mg [SE] | |

### *ACE inhibitors and calcium channel blockers*

## LERCANIDIPINE + ENALAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28**

| 9144G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.23 | 20.77 | Zan-Extra 10/10 [GO] |

**lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28**

| 9145H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.96 | 21.50 | Zan-Extra 10/20 [GO] |

## LERCANIDIPINE + ENALAPRIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28**

| 13507X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.10 | 25.00 | Zan-Extra 10/10 [GO] |

**lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28**

| 13477H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *25.56 | 25.00 | Zan-Extra 10/20 [GO] |

## PERINDOPRIL + AMLODIPINE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**perindopril arginine 5 mg + amlodipine 5 mg tablet, 30**

| 9346X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APO-Perindopril Arginine/Amlodipine 5/5 [TX] | [a] APX-Perindopril Arginine/Amlodipine 5/5 [XT] |
| | | | | | | [a] Perindopril Arginine/Amlodipine-WGR 5/5 [WG] | [a] Reaptan 5/5 [RX] |
| | | | [B]10.65 | 28.75 | 19.64 | [a] Coveram 5/5 [SE] | |

**perindopril arginine 5 mg + amlodipine 10 mg tablet, 30**

| 9347Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.73 | 20.27 | [a] APO-Perindopril Arginine/Amlodipine 5/10 [TX] | [a] APX-Perindopril Arginine/Amlodipine 5/10 [XT] |
| | | | | | | [a] Perindopril Arginine/Amlodipine-WGR 5/10 [WG] | [a] Reaptan 5/10 [RX] |
| | | | [B]10.98 | 29.71 | 20.27 | [a] Coveram 5/10 [SE] | |

**perindopril arginine 10 mg + amlodipine 5 mg tablet, 30**

| 9348B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.50 | 21.04 | [a] APO-Perindopril Arginine/Amlodipine 10/5 [TX] | [a] APX-Perindopril Arginine/Amlodipine 10/5 [XT] |
| | | | | | | [a] Perindopril Arginine/Amlodipine-WGR 10/5 [WG] | [a] Reaptan 10/5 [RX] |
| | | | [B]11.16 | 30.66 | 21.04 | [a] Coveram 10/5 [SE] | |

**perindopril arginine 10 mg + amlodipine 10 mg tablet, 30**

| 9349C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.14 | 21.68 | [a] APO-Perindopril Arginine/Amlodipine 10/10 [TX] | [a] APX-Perindopril Arginine/Amlodipine 10/10 [XT] |
| | | | | | | [a] Perindopril Arginine/Amlodipine-WGR 10/10 [WG] | [a] Reaptan 10/10 [RX] |
| | | | [B]11.49 | 31.63 | 21.68 | [a] Coveram 10/10 [SE] | |

## PERINDOPRIL + AMLODIPINE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**perindopril arginine 5 mg + amlodipine 5 mg tablet, 30**

| 13508Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] APO-Perindopril Arginine/Amlodipine 5/5 [TX] | [a] APX-Perindopril Arginine/Amlodipine 5/5 [XT] |
| | | | | | | [a] Perindopril Arginine/Amlodipine-WGR 5/5 [WG] | [a] Reaptan 5/5 [RX] |
| | | | [B]21.30 | 43.14 | 23.38 | [a] Coveram 5/5 [SE] | |

**perindopril arginine 5 mg + amlodipine 10 mg tablet, 30**

| 13381G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *23.10 | 24.64 | [a] APO-Perindopril Arginine/Amlodipine 5/10 [TX] | [a] APX-Perindopril Arginine/Amlodipine 5/10 [XT] |
| | | | | | | [a] Perindopril Arginine/Amlodipine-WGR 5/10 [WG] | [a] Reaptan 5/10 [RX] |
| | | | [B]21.96 | 45.06 | 24.64 | [a] Coveram 5/10 [SE] | |

**perindopril arginine 10 mg + amlodipine 5 mg tablet, 30**

| 13478J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.64 | 25.00 | [a] APO-Perindopril Arginine/Amlodipine 10/5 [TX] | [a] APX-Perindopril Arginine/Amlodipine 10/5 [XT] |
| | | | | | | [a] Perindopril Arginine/Amlodipine-WGR 10/5 [WG] | [a] Reaptan 10/5 [RX] |
| | | | [B]22.32 | 46.96 | 25.00 | [a] Coveram 10/5 [SE] | |

**perindopril arginine 10 mg + amlodipine 10 mg tablet, 30**

| 13382H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *25.92 | 25.00 | [a] APO-Perindopril Arginine/Amlodipine 10/10 [TX] | [a] APX-Perindopril Arginine/Amlodipine 10/10 [XT] |
| | | | | | | [a] Perindopril Arginine/Amlodipine-WGR 10/10 [WG] | [a] Reaptan 10/10 [RX] |
| | | | [B]22.98 | 48.90 | 25.00 | [a] Coveram 10/10 [SE] | |

## RAMIPRIL + FELODIPINE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**ramipril 5 mg + felodipine 5 mg modified release tablet, 30**

| 2629J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.09 | 21.63 | Triasyn 5.0/5.0 [SW] |

## RAMIPRIL + FELODIPINE

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ramipril 5 mg + felodipine 5 mg modified release tablet, 30**

| 13534H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *25.82 | 25.00 | Triasyn 5.0/5.0 [SW] |

## TRANDOLAPRIL + VERAPAMIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Caution** The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

**trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28**

| 9387C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 24.47 | 25.00 | Tarka 2/180 [GO] |

**trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28**

| 2857J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 30.36 | 25.00 | Tarka 4/240 [GO] |

## TRANDOLAPRIL + VERAPAMIL

**Caution** Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Caution** The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28**

| 13594L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *34.58 | 25.00 | Tarka 2/180 [GO] |

**trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28**

| 13591H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *46.36 | 25.00 | Tarka 4/240 [GO] |

# ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN

***Angiotensin II receptor blockers (ARBs), plain***

## CANDESARTAN

**candesartan cilexetil 4 mg tablet, 30**

| 8295N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] BTC Candesartan [BG] | [a] CANDESAN [RF] |
| | | | | | | [a] Candesartan Sandoz [SZ] | [a] CANDESARTAN-WGR [WG] |
| | | | [B]12.94 | 30.04 | 18.64 | [a] Atacand [LM] | |

**candesartan cilexetil 8 mg tablet, 30**

| 8296P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] BTC Candesartan [BG] | [a] CANDESAN [RF] |
| | | | | | | [a] Candesartan Sandoz [SZ] | [a] CANDESARTAN-WGR [WG] |
| | | | [B]12.94 | 30.04 | 18.64 | [a] Atacand [LM] | |

**candesartan cilexetil 16 mg tablet, 30**

| 8297Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.44 | 19.98 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] BTC Candesartan [BG] | [a] CANDESAN [RF] |
| | | | | | | [a] Candesartan Sandoz [SZ] | [a] CANDESARTAN-WGR [WG] |
| | | | [B]12.99 | 31.43 | 19.98 | [a] Atacand [LM] | |

**candesartan cilexetil 32 mg tablet, 30**

| 8889W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] BTC Candesartan [BG] | [a] CANDESAN [RF] |
| | | | | | | [a] Candesartan Sandoz [SZ] | [a] CANDESARTAN-WGR [WG] |
| | | | [B]11.20 | 29.80 | 20.14 | [a] Atacand [LM] | |

## CANDESARTAN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**candesartan cilexetil 4 mg tablet, 30**

| 13592J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] BTC Candesartan [BG] | [a] CANDESAN [RF] |
| | | | | | | [a] Candesartan Sandoz [SZ] | [a] CANDESARTAN-WGR [WG] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13592J | | | [B]25.88 | 45.72 | 21.38 | [a] Atacand [LM] | |

**candesartan cilexetil 8 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13436E | | | | | | | |
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] BTC Candesartan [BG] | [a] CANDESAN [RF] |
| | | | | | | [a] Candesartan Sandoz [SZ] | [a] CANDESARTAN-WGR [WG] |
| | | | [B]25.88 | 45.72 | 21.38 | [a] Atacand [LM] | |

**candesartan cilexetil 16 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13565Y | | | | | | | |
| NP | 2 | 5 | 0.00 | *22.52 | 24.06 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] BTC Candesartan [BG] | [a] CANDESAN [RF] |
| | | | | | | [a] Candesartan Sandoz [SZ] | [a] CANDESARTAN-WGR [WG] |
| | | | [B]25.98 | 48.50 | 24.06 | [a] Atacand [LM] | |

**candesartan cilexetil 32 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13438G | | | | | | | |
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] Adesan [AF] | [a] APO-Candesartan [TX] |
| | | | | | | [a] BTC Candesartan [BG] | [a] CANDESAN [RF] |
| | | | | | | [a] Candesartan Sandoz [SZ] | [a] CANDESARTAN-WGR [WG] |
| | | | [B]22.40 | 45.24 | 24.38 | [a] Atacand [LM] | |

## EPROSARTAN

**eprosartan 600 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8447N | | | | | | |
| NP | 1 | 5 | 0.00 | 28.21 | 25.00 | Teveten [GO] |

## EPROSARTAN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**eprosartan 600 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13912F | | | | | | |
| NP | 2 | 5 | 0.00 | *42.06 | 25.00 | Teveten [GO] |

## EPROSARTAN

**Authority Required**

***6351***

Adverse effects occurring with all of the base-priced drugs

**Authority Required**

***6332***

Drug interactions occurring with all of the base-priced drugs

**Authority Required**

***6328***

Drug interactions expected to occur with all of the base-priced drugs

**Authority Required**

***6329***

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

**eprosartan 600 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5491B | | | | | | |
| NP | 1 | 5 | 0.00 | 28.21 | 25.00 | Teveten [GO] |

## EPROSARTAN

**Authority Required**

***14969***

Adverse effects occurring with all of the base-priced drugs

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required**

***14970***
Drug interactions occurring with all of the base-priced drugs
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required**
***14841***
Drug interactions expected to occur with all of the base-priced drugs
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required**
***15009***
Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**eprosartan 600 mg tablet, 28**

| 13861M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *42.06 | 25.00 | Teveten [GO] |

## IRBESARTAN

**irbesartan 75 mg tablet, 30**

| 8246B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] Abisart 75 [AL] | [a] APO-Irbesartan [TX] |
| | | | | | | [a] AVSARTAN [RF] | [a] Blooms Irbesartan [BG] |
| | | | | | | [a] Irbesartan Sandoz [SZ] | [a] IRBESARTAN-WGR [WG] |

**irbesartan 150 mg tablet, 30**

| 8247C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] Abisart 150 [AL] | [a] APO-Irbesartan [TX] |
| | | | | | | [a] AVSARTAN [RF] | [a] Blooms Irbesartan [BG] |
| | | | | | | [a] Irbesartan Sandoz [SZ] | [a] IRBESARTAN-WGR [WG] |
| | | | [B]3.81 | 20.91 | 18.64 | [a] Avapro [AV] | |
| | | | [B]3.81 | 20.91 | 18.64 | [a] Karvea [SW] | |

**irbesartan 300 mg tablet, 30**

| 8248D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] Abisart 300 [AL] | [a] APO-Irbesartan [TX] |
| | | | | | | [a] AVSARTAN [RF] | [a] Blooms Irbesartan [BG] |
| | | | | | | [a] Irbesartan Sandoz [SZ] | [a] IRBESARTAN-WGR [WG] |
| | | | [B]3.82 | 21.92 | 19.64 | [a] Avapro [AV] | |
| | | | [B]3.82 | 21.92 | 19.64 | [a] Karvea [SW] | |

## IRBESARTAN

**Restricted benefit**
***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**irbesartan 75 mg tablet, 30**

| 13435D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Abisart 75 [AL] | [a] APO-Irbesartan [TX] |
| | | | | | | [a] AVSARTAN [RF] | [a] Blooms Irbesartan [BG] |
| | | | | | | [a] Irbesartan Sandoz [SZ] | [a] IRBESARTAN-WGR [WG] |

**irbesartan 150 mg tablet, 30**

| 13380F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Abisart 150 [AL] | [a] APO-Irbesartan [TX] |
| | | | | | | [a] AVSARTAN [RF] | [a] Blooms Irbesartan [BG] |
| | | | | | | [a] Irbesartan Sandoz [SZ] | [a] IRBESARTAN-WGR [WG] |
| | | | [B]7.62 | 27.46 | 21.38 | [a] Avapro [AV] | |
| | | | [B]7.62 | 27.46 | 21.38 | [a] Karvea [SW] | |

### irbesartan 300 mg tablet, 30

| 13564X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] Abisart 300 [AL] | [a] APO-Irbesartan [TX] |
| | | | | | | [a] AVSARTAN [RF] | [a] Blooms Irbesartan [BG] |
| | | | | | | [a] Irbesartan Sandoz [SZ] | [a] IRBESARTAN-WGR [WG] |
| | | | [B]7.64 | 29.48 | 23.38 | [a] Avapro [AV] | |
| | | | [B]7.64 | 29.48 | 23.38 | [a] Karvea [SW] | |

## OLMESARTAN

### olmesartan medoxomil 20 mg tablet, 30

| 2147B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.43 | 19.97 | [a] APO-Olmesartan [TX] | [a] Blooms The Chemist Olmesartan [BG] |
| | | | | | | [a] OLMERTAN [RW] | [a] Olmesartan - MYL [AF] |
| | | | | | | [a] Olmesartan Sandoz [SZ] | [a] OLMESARTAN-WGR [WG] |
| | | | | | | [a] Olsetan [MQ] | [a] Pharmacor Olmesartan 20 [CR] |
| | | | [B]3.80 | 22.23 | 19.97 | [a] Olmetec [AL] | |

### olmesartan medoxomil 40 mg tablet, 30

| 2148C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.27 | 21.81 | [a] APO-Olmesartan [TX] | [a] Blooms The Chemist Olmesartan [BG] |
| | | | | | | [a] OLMERTAN [RW] | [a] Olmesartan - MYL [AF] |
| | | | | | | [a] Olmesartan Sandoz [SZ] | [a] OLMESARTAN-WGR [WG] |
| | | | | | | [a] Olsetan [MQ] | [a] Pharmacor Olmesartan 40 [CR] |
| | | | [B]4.37 | 24.64 | 21.81 | [a] Olmetec [AL] | |

## OLMESARTAN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### olmesartan medoxomil 20 mg tablet, 30

| 13505T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.50 | 24.04 | [a] APO-Olmesartan [TX] | [a] Blooms The Chemist Olmesartan [BG] |
| | | | | | | [a] OLMERTAN [RW] | [a] Olmesartan - MYL [AF] |
| | | | | | | [a] Olmesartan Sandoz [SZ] | [a] OLMESARTAN-WGR [WG] |
| | | | | | | [a] Olsetan [MQ] | [a] Pharmacor Olmesartan 20 [CR] |
| | | | [B]7.60 | 30.10 | 24.04 | [a] Olmetec [AL] | |

### olmesartan medoxomil 40 mg tablet, 30

| 13533G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *26.18 | 25.00 | [a] APO-Olmesartan [TX] | [a] Blooms The Chemist Olmesartan [BG] |
| | | | | | | [a] OLMERTAN [RW] | [a] Olmesartan - MYL [AF] |
| | | | | | | [a] Olmesartan Sandoz [SZ] | [a] OLMESARTAN-WGR [WG] |
| | | | | | | [a] Olsetan [MQ] | [a] Pharmacor Olmesartan 40 [CR] |
| | | | [B]8.74 | 34.92 | 25.00 | [a] Olmetec [AL] | |

## TELMISARTAN

### telmisartan 40 mg tablet, 28

| 8355R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Telmisartan [TX] | [a] Mizart [AF] |
| | | | | | | [a] Pharmacor Telmisartan 40 [CR] | [a] Telmisartan Sandoz [SZ] |
| | | | | | | [a] TELMISARTAN-WGR [WG] | [a] Teltartan [RW] |
| | | | [B]9.59 | 26.69 | 18.64 | [a] Micardis [BY] | |

**telmisartan 80 mg tablet, 28**

| 8356T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Telmisartan [TX] | [a] Mizart [AF] |
| | | | | | | [a] Pharmacor Telmisartan 80 [CR] | [a] Telmisartan Sandoz [SZ] |
| | | | | | | [a] TELMISARTAN-WGR [WG] | [a] Teltartan [RW] |
| | | | [B]9.63 | 28.23 | 20.14 | [a] Micardis [BY] | |

## TELMISARTAN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**telmisartan 40 mg tablet, 28**

| 13437F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APO-Telmisartan [TX] | [a] Mizart [AF] |
| | | | | | | [a] Pharmacor Telmisartan 40 [CR] | [a] Telmisartan Sandoz [SZ] |
| | | | | | | [a] TELMISARTAN-WGR [WG] | [a] Teltartan [RW] |
| | | | [B]19.18 | 39.02 | 21.38 | [a] Micardis [BY] | |

**telmisartan 80 mg tablet, 28**

| 13593K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Telmisartan [TX] | [a] Mizart [AF] |
| | | | | | | [a] Pharmacor Telmisartan 80 [CR] | [a] Telmisartan Sandoz [SZ] |
| | | | | | | [a] TELMISARTAN-WGR [WG] | [a] Teltartan [RW] |
| | | | [B]19.26 | 42.10 | 24.38 | [a] Micardis [BY] | |

## VALSARTAN

**valsartan 40 mg tablet, 28**

| 9368C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 19.16 | 20.70 | [a] Dilart [AF] | [a] Diovan [NV] |

**valsartan 80 mg tablet, 28**

| 9369D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.58 | 21.12 | [a] Dilart [AF] | [a] Diovan [NV] |

**valsartan 160 mg tablet, 28**

| 9370E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.02 | 22.56 | [a] Dilart [AF] | [a] Diovan [NV] |

## VALSARTAN

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

**valsartan 320 mg tablet, 28**

| 9371F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 22.90 | 24.44 | [a] Dilart [AF] | [a] Diovan [NV] |

## VALSARTAN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**valsartan 80 mg tablet, 28**

| 13414B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.80 | 25.00 | [a] Dilart [AF] | [a] Diovan [NV] |

**valsartan 160 mg tablet, 28**

| 13566B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *27.68 | 25.00 | [a] Dilart [AF] | [a] Diovan [NV] |

## VALSARTAN

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**valsartan 320 mg tablet, 28**

| 13383J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *31.44 | 25.00 | [a] Dilart [AF] | [a] Diovan [NV] |

## ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), COMBINATIONS

### *Angiotensin II receptor blockers (ARBs) and diuretics*

## CANDESARTAN + HYDROCHLOROTHIAZIDE

**candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 8504N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] Adesan HCT 16/12.5 [AF] | [a] APO-Candesartan HCTZ 16/12.5 [TX] |
| | | | | | | [a] BTC Candesartan HCT [BG] | [a] CANDESAN COMBI 16/12.5 [RF] |
| | | | | | | [a] Candesartan/HCT Sandoz [SZ] | [a] CANDESARTAN HCTZ-WGR 16/12.5 [WG] |
| | | | [B]12.63 | 31.23 | 20.14 | [a] Atacand Plus 16/12.5 [LM] | |

**candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 9314F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] Adesan HCT 32/12.5 [AF] | [a] APO-Candesartan HCTZ 32/12.5 [TX] |
| | | | | | | [a] BTC Candesartan HCT [BG] | [a] CANDESAN COMBI 32/12.5 [RF] |
| | | | | | | [a] Candesartan/HCT Sandoz [SZ] | [a] CANDESARTAN HCTZ-WGR 32/12.5 [WG] |
| | | | [B]10.78 | 29.38 | 20.14 | [a] Atacand Plus 32/12.5 [LM] | |

**candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30**

| 9315G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.10 | 20.64 | [a] Adesan HCT 32/25 [AF] | [a] APO-Candesartan HCTZ 32/25 [TX] |
| | | | | | | [a] BTC Candesartan HCT [BG] | [a] CANDESAN COMBI 32/25 [RF] |
| | | | | | | [a] Candesartan/HCT Sandoz [SZ] | [a] CANDESARTAN HCTZ-WGR 32/25 [WG] |
| | | | [B]10.48 | 29.58 | 20.64 | [a] Atacand Plus 32/25 [LM] | |

## CANDESARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 13391T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] Adesan HCT 16/12.5 [AF] | [a] APO-Candesartan HCTZ 16/12.5 [TX] |
| | | | | | | [a] BTC Candesartan HCT [BG] | [a] CANDESAN COMBI 16/12.5 [RF] |
| | | | | | | [a] Candesartan/HCT Sandoz [SZ] | [a] CANDESARTAN HCTZ-WGR 16/12.5 [WG] |
| | | | [B]25.26 | 48.10 | 24.38 | [a] Atacand Plus 16/12.5 [LM] | |

**candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 13452B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] Adesan HCT 32/12.5 [AF] | [a] APO-Candesartan HCTZ 32/12.5 [TX] |
| | | | | | | [a] BTC Candesartan HCT [BG] | [a] CANDESAN COMBI 32/12.5 [RF] |
| | | | | | | [a] Candesartan/HCT Sandoz [SZ] | [a] CANDESARTAN HCTZ-WGR 32/12.5 [WG] |
| | | | [B]21.56 | 44.40 | 24.38 | [a] Atacand Plus 32/12.5 [LM] | |

**candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30**

| 13392W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *23.84 | 25.00 | [a] Adesan HCT 32/25 [AF] | [a] APO-Candesartan HCTZ 32/25 [TX] |
| | | | | | | [a] BTC Candesartan HCT [BG] | [a] CANDESAN COMBI 32/25 [RF] |
| | | | | | | [a] Candesartan/HCT Sandoz [SZ] | [a] CANDESARTAN HCTZ-WGR 32/25 [WG] |
| | | | [B]20.96 | 44.80 | 25.00 | [a] Atacand Plus 32/25 [LM] | |

## EPROSARTAN + HYDROCHLOROTHIAZIDE

**eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 8624X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 26.77 | 25.00 | Teveten Plus 600/12.5 [GO] |

## EPROSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 14337N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *39.18 | 25.00 | Teveten Plus 600/12.5 [GO] |

## IRBESARTAN + HYDROCHLOROTHIAZIDE

**irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 8404H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] Abisart HCTZ 150/12.5 [AL] | [a] APO-Irbesartan HCTZ [TX] |
| | | | | | | [a] AVSARTAN HCT 150/12.5 [RF] | [a] Irbesartan/HCT Sandoz [SZ] |
| | | | | | | [a] IRBESARTAN HCTZ-WGR 150/12.5 [WG] | |
| | | | [B]3.81 | 20.91 | 18.64 | [a] Avapro HCT 150/12.5 [AV] | |
| | | | [B]3.81 | 20.91 | 18.64 | [a] Karvezide 150/12.5 [SW] | |

**irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 8405J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.20 | 19.74 | [a] Abisart HCTZ 300/12.5 [AL] | [a] APO-Irbesartan HCTZ [TX] |
| | | | | | | [a] AVSARTAN HCT 300/12.5 [RF] | [a] Irbesartan/HCT Sandoz [SZ] |
| | | | | | | [a] IRBESARTAN HCTZ-WGR 300/12.5 [WG] | |
| | | | [B]3.83 | 22.03 | 19.74 | [a] Avapro HCT 300/12.5 [AV] | |
| | | | [B]3.83 | 22.03 | 19.74 | [a] Karvezide 300/12.5 [SW] | |

**irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30**

| 2136K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.52 | 20.06 | [a] Abisart HCTZ 300/25 [AL] | [a] APO-Irbesartan HCTZ [TX] |
| | | | | | | [a] AVSARTAN HCT 300/25 [RF] | [a] Irbesartan/HCT Sandoz [SZ] |
| | | | | | | [a] IRBESARTAN HCTZ-WGR 300/25 [WG] | |
| | | | [B]3.84 | 22.36 | 20.06 | [a] Avapro HCT 300/25 [AV] | |
| | | | [B]3.84 | 22.36 | 20.06 | [a] Karvezide 300/25 [SW] | |

## IRBESARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 13572H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Abisart HCTZ 150/12.5 [AL] | [a] APO-Irbesartan HCTZ [TX] |

| 13572H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] AVSARTAN HCT 150/12.5 [RF] | [a] Irbesartan/HCT Sandoz [SZ] |
| | | | | | | [a] IRBESARTAN HCTZ-WGR 150/12.5 [WG] | |
| | | | [B]7.62 | 27.46 | 21.38 | [a] Avapro HCT 150/12.5 [AV] | |
| | | | [B]7.62 | 27.46 | 21.38 | [a] Karvezide 150/12.5 [SW] | |

**irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 13545X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.04 | 23.58 | [a] Abisart HCTZ 300/12.5 [AL] | [a] APO-Irbesartan HCTZ [TX] |
| | | | | | | [a] AVSARTAN HCT 300/12.5 [RF] | [a] Irbesartan/HCT Sandoz [SZ] |
| | | | | | | [a] IRBESARTAN HCTZ-WGR 300/12.5 [WG] | |
| | | | [B]7.66 | 29.70 | 23.58 | [a] Avapro HCT 300/12.5 [AV] | |
| | | | [B]7.66 | 29.70 | 23.58 | [a] Karvezide 300/12.5 [SW] | |

**irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30**

| 13446Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.68 | 24.22 | [a] Abisart HCTZ 300/25 [AL] | [a] APO-Irbesartan HCTZ [TX] |
| | | | | | | [a] AVSARTAN HCT 300/25 [RF] | [a] Irbesartan/HCT Sandoz [SZ] |
| | | | | | | [a] IRBESARTAN HCTZ-WGR 300/25 [WG] | |
| | | | [B]7.68 | 30.36 | 24.22 | [a] Avapro HCT 300/25 [AV] | |
| | | | [B]7.68 | 30.36 | 24.22 | [a] Karvezide 300/25 [SW] | |

## OLMESARTAN + HYDROCHLOROTHIAZIDE

**olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 2161R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Olmesartan/HCTZ 20/12.5 [TX] | [a] OLMERTAN COMBI 20/12.5 [RW] |
| | | | | | | [a] Olmesartan HCT - MYL 20/12.5 [AF] | [a] Olmesartan/HCT Sandoz [SZ] |
| | | | | | | [a] Olmesartan HCT Viatris [MQ] | [a] OLMESARTAN HCTZ-WGR 20/12.5 [WG] |
| | | | | | | [a] Pharmacor Olmesartan HCTZ 20/12.5 [CR] | |
| | | | [B]2.84 | 21.44 | 20.14 | [a] Olmetec Plus [AL] | |

**olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 2166B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.32 | 20.86 | [a] APO-Olmesartan/HCTZ 40/12.5 [TX] | [a] OLMERTAN COMBI 40/12.5 [RW] |
| | | | | | | [a] Olmesartan HCT - MYL 40/12.5 [AF] | [a] Olmesartan/HCT Sandoz [SZ] |
| | | | | | | [a] Olmesartan HCT Viatris [MQ] | [a] OLMESARTAN HCTZ-WGR 40/12.5 [WG] |
| | | | | | | [a] Pharmacor Olmesartan HCTZ 40/12.5 [CR] | |
| | | | [B]3.71 | 23.03 | 20.86 | [a] Olmetec Plus [AL] | |

**olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30**

| 2170F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.93 | 21.47 | [a] APO-Olmesartan/HCTZ 40/25 [TX] | [a] OLMERTAN COMBI 40/25 [RW] |
| | | | | | | [a] Olmesartan HCT - MYL 40/25 [AF] | [a] Olmesartan/HCT Sandoz [SZ] |
| | | | | | | [a] Olmesartan HCT Viatris [MQ] | [a] OLMESARTAN HCTZ-WGR 40/25 [WG] |
| | | | | | | [a] Pharmacor Olmesartan HCTZ 40/25 [CR] | |
| | | | [B]3.74 | 23.67 | 21.47 | [a] Olmetec Plus [AL] | |

## OLMESARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 13447R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Olmesartan/HCTZ 20/12.5 [TX] | [a] OLMERTAN COMBI 20/12.5 [RW] |
| | | | | | | [a] Olmesartan HCT - MYL 20/12.5 [AF] | [a] Olmesartan/HCT Sandoz [SZ] |
| | | | | | | [a] Olmesartan HCT Viatris [MQ] | [a] OLMESARTAN HCTZ-WGR 20/12.5 [WG] |
| | | | | | | [a] Pharmacor Olmesartan HCTZ 20/12.5 [CR] | |
| | | | [B]5.68 | 28.52 | 24.38 | [a] Olmetec Plus [AL] | |

**olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 13601W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.28 | 25.00 | [a] APO-Olmesartan/HCTZ 40/12.5 [TX] | [a] OLMERTAN COMBI 40/12.5 [RW] |
| | | | | | | [a] Olmesartan HCT - MYL 40/12.5 [AF] | [a] Olmesartan/HCT Sandoz [SZ] |
| | | | | | | [a] Olmesartan HCT Viatris [MQ] | [a] OLMESARTAN HCTZ-WGR 40/12.5 [WG] |
| | | | | | | [a] Pharmacor Olmesartan HCTZ 40/12.5 [CR] | |
| | | | [B]7.42 | 31.70 | 25.00 | [a] Olmetec Plus [AL] | |

**olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30**

| 13602X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *25.50 | 25.00 | [a] APO-Olmesartan/HCTZ 40/25 [TX] | [a] OLMERTAN COMBI 40/25 [RW] |
| | | | | | | [a] Olmesartan HCT - MYL 40/25 [AF] | [a] Olmesartan/HCT Sandoz [SZ] |
| | | | | | | [a] Olmesartan HCT Viatris [MQ] | [a] OLMESARTAN HCTZ-WGR 40/25 [WG] |
| | | | | | | [a] Pharmacor Olmesartan HCTZ 40/25 [CR] | |
| | | | [B]7.48 | 32.98 | 25.00 | [a] Olmetec Plus [AL] | |

## TELMISARTAN + HYDROCHLOROTHIAZIDE

**telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 8622T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.22 | 18.76 | [a] APO-Telmisartan HCTZ 40/12.5 [TX] | [a] Mizart HCT 40/12.5 mg [AF] |
| | | | | | | [a] Telmisartan/HCT Sandoz [SZ] | [a] TELMISARTAN HCTZ-WGR 40/12.5 [WG] |
| | | | | | | [a] Teltartan HCT 40/12.5 [RW] | |
| | | | [B]9.58 | 26.80 | 18.76 | [a] Micardis Plus 40/12.5 mg [BY] | |

**telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 8623W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Telmisartan HCTZ 80/12.5 [TX] | [a] Mizart HCT 80/12.5 mg [AF] |
| | | | | | | [a] Telmisartan/HCT Sandoz [SZ] | [a] TELMISARTAN HCTZ-WGR 80/12.5 [WG] |
| | | | | | | [a] Teltartan HCT 80/12.5 [RW] | |
| | | | [B]9.63 | 28.23 | 20.14 | [a] Micardis Plus 80/12.5 mg [BY] | |

**telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28**

| 9381R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.91 | 20.45 | [a] APO-Telmisartan HCTZ 80/25 [TX] | [a] Mizart HCT 80/25 mg [AF] |
| | | | | | | [a] Telmisartan/HCT Sandoz [SZ] | [a] TELMISARTAN HCTZ-WGR 80/25 [WG] |
| | | | | | | [a] Teltartan HCT 80/25 [RW] | |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9381R | | | [B]9.65 | 28.56 | 20.45 | [a] Micardis Plus 80/25 mg [BY] | |

## TELMISARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13546Y | | | | | | | |
| NP | 2 | 5 | 0.00 | *20.08 | 21.62 | [a] APO-Telmisartan HCTZ 40/12.5 [TX] | [a] Mizart HCT 40/12.5 mg [AF] |
| | | | | | | [a] Telmisartan/HCT Sandoz [SZ] | [a] TELMISARTAN HCTZ-WGR 40/12.5 [WG] |
| | | | | | | [a] Teltartan HCT 40/12.5 [RW] | |
| | | | [B]19.16 | 39.24 | 21.62 | [a] Micardis Plus 40/12.5 mg [BY] | |

### telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13574K | | | | | | | |
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Telmisartan HCTZ 80/12.5 [TX] | [a] Mizart HCT 80/12.5 mg [AF] |
| | | | | | | [a] Telmisartan/HCT Sandoz [SZ] | [a] TELMISARTAN HCTZ-WGR 80/12.5 [WG] |
| | | | | | | [a] Teltartan HCT 80/12.5 [RW] | |
| | | | [B]19.26 | 42.10 | 24.38 | [a] Micardis Plus 80/12.5 mg [BY] | |

### telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13607E | | | | | | | |
| NP | 2 | 5 | 0.00 | *23.46 | 25.00 | [a] APO-Telmisartan HCTZ 80/25 [TX] | [a] Mizart HCT 80/25 mg [AF] |
| | | | | | | [a] Telmisartan/HCT Sandoz [SZ] | [a] TELMISARTAN HCTZ-WGR 80/25 [WG] |
| | | | | | | [a] Teltartan HCT 80/25 [RW] | |
| | | | [B]19.30 | 42.76 | 25.00 | [a] Micardis Plus 80/25 mg [BY] | |

## VALSARTAN + HYDROCHLOROTHIAZIDE

### valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9372G | | | | | | | |
| NP | 1 | 5 | 0.00 | 20.83 | 22.37 | [a] Co-Diovan 80/12.5 [NV] | [a] Dilart HCT 80/12.5 [AF] |

### valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9373H | | | | | | | |
| NP | 1 | 5 | 0.00 | 22.36 | 23.90 | [a] Co-Diovan 160/12.5 [NV] | [a] Dilart HCT 160/12.5 [AF] |

### valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9374J | | | | | | | |
| NP | 1 | 5 | 0.00 | 23.43 | 24.97 | [a] Co-Diovan 160/25 [NV] | [a] Dilart HCT 160/25 [AF] |

## VALSARTAN + HYDROCHLOROTHIAZIDE

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

### valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9481B | | | | | | | |
| NP | 1 | 5 | 0.00 | 24.32 | 25.00 | [a] Co-Diovan 320/12.5 [NV] | [a] Dilart HCT 320/12.5 [AF] |

### valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9482C | | | | | | | |
| NP | 1 | 5 | 0.00 | 25.38 | 25.00 | [a] Co-Diovan 320/25 [NV] | [a] Dilart HCT 320/25 [AF] |

## VALSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 13393X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *27.30 | 25.00 | [a] Co-Diovan 80/12.5 [NV] | [a] Dilart HCT 80/12.5 [AF] |

**valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 13606D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *30.36 | 25.00 | [a] Co-Diovan 160/12.5 [NV] | [a] Dilart HCT 160/12.5 [AF] |

**valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

| 13453C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *32.50 | 25.00 | [a] Co-Diovan 160/25 [NV] | [a] Dilart HCT 160/25 [AF] |

## VALSARTAN + HYDROCHLOROTHIAZIDE

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 13517K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *34.28 | 25.00 | [a] Co-Diovan 320/12.5 [NV] | [a] Dilart HCT 320/12.5 [AF] |

**valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28**

| 13455E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *36.40 | 25.00 | [a] Co-Diovan 320/25 [NV] | [a] Dilart HCT 320/25 [AF] |

### *Angiotensin II receptor blockers (ARBs) and calcium channel blockers*

## AMLODIPINE + VALSARTAN

**amlodipine 5 mg + valsartan 80 mg tablet, 28**

| 9375K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 22.10 | 23.64 | [a] Amlodipine/Valsartan Novartis 5/80 [NM] | |
| | | | [B]7.76 | 29.86 | 23.64 | [a] Exforge 5/80 [NV] | |

**amlodipine 5 mg + valsartan 160 mg tablet, 28**

| 9376L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 24.07 | 25.00 | [a] Amlodipine/Valsartan Novartis 5/160 [NM] | |
| | | | [B]7.76 | 31.83 | 25.00 | [a] Exforge 5/160 [NV] | |

**amlodipine 5 mg + valsartan 320 mg tablet, 28**

| 5459H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 26.58 | 25.00 | [a] Amlodipine/Valsartan Novartis 5/320 [NM] | |
| | | | [B]7.76 | 34.34 | 25.00 | [a] Exforge 5/320 [NV] | |

**amlodipine 10 mg + valsartan 160 mg tablet, 28**

| 9377M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 24.58 | 25.00 | [a] Amlodipine/Valsartan Novartis 10/160 [NM] | |
| | | | [B]7.76 | 32.34 | 25.00 | [a] Exforge 10/160 [NV] | |

**amlodipine 10 mg + valsartan 320 mg tablet, 28**

| 5460J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 26.78 | 25.00 | [a] Amlodipine/Valsartan Novartis 10/320 [NM] | |
| | | | [B]7.76 | 34.54 | 25.00 | [a] Exforge 10/320 [NV] | |

## AMLODIPINE + VALSARTAN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**amlodipine 5 mg + valsartan 80 mg tablet, 28**

| 13421J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *29.84 | 25.00 | [a] Amlodipine/Valsartan Novartis 5/80 [NM] | |
| | | | [B]15.52 | *45.36 | 25.00 | [a] Exforge 5/80 [NV] | |

**amlodipine 5 mg + valsartan 160 mg tablet, 28**

| 13516J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *33.78 | 25.00 | [a] Amlodipine/Valsartan Novartis 5/160 [NM] | |
| | | | [B]15.52 | *49.30 | 25.00 | [a] Exforge 5/160 [NV] | |

**amlodipine 5 mg + valsartan 320 mg tablet, 28**

| 13604B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *38.80 | 25.00 | [a] Amlodipine/Valsartan Novartis 5/320 [NM] | |
| | | | [B]15.52 | *54.32 | 25.00 | [a] Exforge 5/320 [NV] | |

**amlodipine 10 mg + valsartan 160 mg tablet, 28**

| 13454D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *34.80 | 25.00 | [a] Amlodipine/Valsartan Novartis 10/160 [NM] | |
| | | | [B]15.52 | *50.32 | 25.00 | [a] Exforge 10/160 [NV] | |

**amlodipine 10 mg + valsartan 320 mg tablet, 28**

| 13389Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *39.20 | 25.00 | [a] Amlodipine/Valsartan Novartis 10/320 [NM] | |
| | | | [B]15.52 | *54.72 | 25.00 | [a] Exforge 10/320 [NV] | |

## OLMESARTAN + AMLODIPINE

**olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30**

| 5292M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.22 | 19.76 | [a] APO-OLMESARTAN/AMLODIPINE 20/5 [TY] | [a] OLMEKAR [RW] |
| | | | | | | [a] Olmesartan/Amlodipine - MYL 20/5 [AF] | [a] Olmesartan/Amlodipine Sandoz [SZ] |
| | | | | | | [a] OLMESARTAN AMLODIPINE-WGR 20/5 [WG] | [a] Pharmacor Olmesartan Amlodipine 20/5 [CR] |
| | | | [B]3.80 | 22.02 | 19.76 | [a] Sevikar 20/5 [AL] | |

**olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30**

| 5293N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.10 | 20.64 | [a] APO-OLMESARTAN/AMLODIPINE 40/5 [TY] | [a] OLMEKAR [RW] |
| | | | | | | [a] Olmesartan/Amlodipine - MYL 40/5 [AF] | [a] Olmesartan/Amlodipine Sandoz [SZ] |
| | | | | | | [a] OLMESARTAN AMLODIPINE-WGR 40/5 [WG] | [a] Pharmacor Olmesartan Amlodipine 40/5 [CR] |
| | | | [B]3.32 | 22.42 | 20.64 | [a] Sevikar 40/5 [AL] | |

**olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30**

| 5294P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.42 | 20.96 | [a] APO-OLMESARTAN/AMLODIPINE 40/10 [TY] | [a] OLMEKAR [RW] |
| | | | | | | [a] Olmesartan/Amlodipine - MYL 40/10 [AF] | [a] Olmesartan/Amlodipine Sandoz [SZ] |
| | | | | | | [a] OLMESARTAN AMLODIPINE-WGR 40/10 [WG] | [a] Pharmacor Olmesartan Amlodipine 40/10 [CR] |
| | | | [B]3.33 | 22.75 | 20.96 | [a] Sevikar 40/10 [AL] | |

## OLMESARTAN + AMLODIPINE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30

| 13449W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.08 | 23.62 | [a] APO-OLMESARTAN/AMLODIPINE 20/5 [TY] | [a] OLMEKAR [RW] |
| | | | | | | [a] Olmesartan/Amlodipine - MYL 20/5 [AF] | [a] Olmesartan/Amlodipine Sandoz [SZ] |
| | | | | | | [a] OLMESARTAN AMLODIPINE-WGR 20/5 [WG] | [a] Pharmacor Olmesartan Amlodipine 20/5 [CR] |
| | | | [B]7.60 | 29.68 | 23.62 | [a] Sevikar 20/5 [AL] | |

### olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30

| 13964Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *23.84 | 25.00 | [a] APO-OLMESARTAN/AMLODIPINE 40/5 [TY] | [a] OLMEKAR [RW] |
| | | | | | | [a] Olmesartan/Amlodipine - MYL 40/5 [AF] | [a] Olmesartan/Amlodipine Sandoz [SZ] |
| | | | | | | [a] OLMESARTAN AMLODIPINE-WGR 40/5 [WG] | [a] Pharmacor Olmesartan Amlodipine 40/5 [CR] |
| | | | [B]6.64 | 30.48 | 25.00 | [a] Sevikar 40/5 [AL] | |

### olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30

| 13943W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.48 | 25.00 | [a] APO-OLMESARTAN/AMLODIPINE 40/10 [TY] | [a] OLMEKAR [RW] |
| | | | | | | [a] Olmesartan/Amlodipine - MYL 40/10 [AF] | [a] Olmesartan/Amlodipine Sandoz [SZ] |
| | | | | | | [a] OLMESARTAN AMLODIPINE-WGR 40/10 [WG] | [a] Pharmacor Olmesartan Amlodipine 40/10 [CR] |
| | | | [B]6.66 | 31.14 | 25.00 | [a] Sevikar 40/10 [AL] | |

## TELMISARTAN + AMLODIPINE

### telmisartan 40 mg + amlodipine 5 mg tablet, 28

| 8978M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.52 | 19.06 | [a] ARX-Telmisartan/Amlodipine [XT] | [a] Telmisartan/Amlodipine Viatris [AF] |
| | | | | | | [a] Twilem 40/5 [AL] | |

### telmisartan 40 mg + amlodipine 10 mg tablet, 28

| 8979N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] ARX-Telmisartan/Amlodipine [XT] | [a] Telmisartan/Amlodipine Viatris [AF] |
| | | | | | | [a] Twilem 40/10 [AL] | |

### telmisartan 80 mg + amlodipine 5 mg tablet, 28

| 8980P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.15 | 21.69 | [a] ARX-Telmisartan/Amlodipine [XT] | [a] Telmisartan/Amlodipine Viatris [AF] |
| | | | | | | [a] Twilem 80/5 [AL] | |

### telmisartan 80 mg + amlodipine 10 mg tablet, 28

| 8981Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.77 | 22.31 | [a] ARX-Telmisartan/Amlodipine [XT] | [a] Telmisartan/Amlodipine Viatris [AF] |
| | | | | | | [a] Twilem 80/10 [AL] | |

## TELMISARTAN + AMLODIPINE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**telmisartan 40 mg + amlodipine 5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13483P NP | 2 | 5 | 0.00 | *20.68 | 22.22 | [a] ARX-Telmisartan/Amlodipine [XT]<br>[a] Twilem 40/5 [AL] | [a] Telmisartan/Amlodipine Viatris [AF] |

**telmisartan 40 mg + amlodipine 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13515H NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] ARX-Telmisartan/Amlodipine [XT]<br>[a] Twilem 40/10 [AL] | [a] Telmisartan/Amlodipine Viatris [AF] |

**telmisartan 80 mg + amlodipine 5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13450X NP | 2 | 5 | 0.00 | *25.94 | 25.00 | [a] ARX-Telmisartan/Amlodipine [XT]<br>[a] Twilem 80/5 [AL] | [a] Telmisartan/Amlodipine Viatris [AF] |

**telmisartan 80 mg + amlodipine 10 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13451Y NP | 2 | 5 | 0.00 | *27.18 | 25.00 | [a] ARX-Telmisartan/Amlodipine [XT]<br>[a] Twilem 80/10 [AL] | [a] Telmisartan/Amlodipine Viatris [AF] |

### *Angiotensin II receptor blockers (ARBs), other combinations*

## AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

***4311***

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5285E NP | 1 | 5 | 0.00 | 25.54 | 25.00 | [a] Amlodipine/Valsartan/HCT Novartis 5/160/12.5 [NM] | |
| | | | [B]11.64 | 37.18 | 25.00 | [a] Exforge HCT 5/160/12.5 [NV] | |

**amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5286F NP | 1 | 5 | 0.00 | 27.01 | 25.00 | [a] Amlodipine/Valsartan/HCT Novartis 5/160/25 [NM] | |
| | | | [B]7.76 | 34.77 | 25.00 | [a] Exforge HCT 5/160/25 [NV] | |

**amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5287G NP | 1 | 5 | 0.00 | 26.05 | 25.00 | [a] Amlodipine/Valsartan/HCT Novartis 10/160/12.5 [NM] | |
| | | | [B]7.76 | 33.81 | 25.00 | [a] Exforge HCT 10/160/12.5 [NV] | |

**amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5288H NP | 1 | 5 | 0.00 | 27.52 | 25.00 | [a] Amlodipine/Valsartan/HCT Novartis 10/160/25 [NM] | |
| | | | [B]11.64 | 39.16 | 25.00 | [a] Exforge HCT 10/160/25 [NV] | |

**amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28**

| 5289J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 29.72 | 25.00 | [a] Amlodipine/Valsartan/HCT Novartis 10/320/25 [NM] | |
| | | | [B]7.76 | 37.48 | 25.00 | [a] Exforge HCT 10/320/25 [NV] | |

## AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

***14272***

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 13448T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *36.72 | 25.00 | [a] Amlodipine/Valsartan/HCT Novartis 5/160/12.5 [NM] | |
| | | | [B]23.28 | *60.00 | 25.00 | [a] Exforge HCT 5/160/12.5 [NV] | |

**amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

| 13603Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *39.66 | 25.00 | [a] Amlodipine/Valsartan/HCT Novartis 5/160/25 [NM] | |
| | | | [B]15.52 | *55.18 | 25.00 | [a] Exforge HCT 5/160/25 [NV] | |

**amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28**

| 13514G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *37.74 | 25.00 | [a] Amlodipine/Valsartan/HCT Novartis 10/160/12.5 [NM] | |
| | | | [B]15.52 | *53.26 | 25.00 | [a] Exforge HCT 10/160/12.5 [NV] | |

**amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28**

| 13390R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *40.68 | 25.00 | [a] Amlodipine/Valsartan/HCT Novartis 10/160/25 [NM] | |
| | | | [B]23.28 | *63.96 | 25.00 | [a] Exforge HCT 10/160/25 [NV] | |

**amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28**

| 13573J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *45.08 | 25.00 | [a] Amlodipine/Valsartan/HCT Novartis 10/320/25 [NM] | |
| | | | [B]15.52 | *60.60 | 25.00 | [a] Exforge HCT 10/320/25 [NV] | |

## OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE

**Restricted benefit**

***4311***

Hypertension

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 10005N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.17 | 21.71 | [a] APO-Olmesartan/Amlodipine/HCTZ 20/5/12.5 [TX] | [a] Olamlo HCT 20/5/12.5 [AL] |
| | | | | | | [a] Sevikar HCT 20/5/12.5 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 2880N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 22.92 | 24.46 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/5/12.5 tablet [TX] | [a] Olamlo HCT 40/5/12.5 [AL] |
| | | | | | | [a] Sevikar HCT 40/5/12.5 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30**

| 2864R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 24.44 | 25.00 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/5/25 tablet [TX] | [a] Olamlo HCT 40/5/25 [AL] |
| | | | [B]3.88 | 28.32 | 25.00 | [a] Sevikar HCT 40/5/25 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 2836G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 23.32 | 24.86 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/10/12.5 [TX] | [a] Olamlo HCT 40/10/12.5 [AL] |
| | | | [B]4.14 | 27.46 | 24.86 | [a] Sevikar HCT 40/10/12.5 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30**

| 2953K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 24.81 | 25.00 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/10/25 [TX] | [a] Olamlo HCT 40/10/25 [AL] |
| | | | | | | [a] Sevikar HCT 40/10/25 [AF] | |

## OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE

**Restricted benefit**

***14272***

Hypertension

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 13481M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *25.98 | 25.00 | [a] APO-Olmesartan/Amlodipine/HCTZ 20/5/12.5 [TX] | [a] Olamlo HCT 20/5/12.5 [AL] |
| | | | | | | [a] Sevikar HCT 20/5/12.5 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 13513F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *31.48 | 25.00 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/5/12.5 tablet [TX] | [a] Olamlo HCT 40/5/12.5 [AL] |
| | | | | | | [a] Sevikar HCT 40/5/12.5 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30**

| 13512E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *34.52 | 25.00 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/5/25 tablet [TX] | [a] Olamlo HCT 40/5/25 [AL] |
| | | | [B]7.76 | *42.28 | 25.00 | [a] Sevikar HCT 40/5/25 [AF] | |

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30**

| 13482N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *32.28 | 25.00 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/10/12.5 [TX] | [a] Olamlo HCT 40/10/12.5 [AL] |
| | | | [B]8.28 | *40.56 | 25.00 | [a] Sevikar HCT 40/10/12.5 [AF] | |

## OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE

**Restricted benefit**

***14837***
Hypertension
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

**olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30**

| 14002Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *35.26 | 25.00 | [a] APO-Olmesartan/Amlodipine/HCTZ 40/10/25 [TX]<br>[a] Sevikar HCT 40/10/25 [AF] | [a] Olamlo HCT 40/10/25 [AL] |

## SACUBITRIL + VALSARTAN

**Authority Required (STREAMLINED)**
***18150***
Chronic heart failure
**Clinical criteria:**

- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker: (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, **AND**
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.

**sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56**

| 11123K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 98.56 | 25.00 | [a] Entresto [NV]<br>[a] Omtralo [NM]<br>[a] Sacubitril/Valsartan Alphapharm [FY]<br>[a] SACUBITRIL/VALSARTAN-WGR [WG] | [a] MSN-SACUBITRIL/VALSARTAN [VM]<br>[a] Pharmacor Sacubitril/Valsartan [CR]<br>[a] Sacubitril/Valsartan Lupin 24/26 [GQ]<br>[a] Valtresto [TX] |

**sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56**

| 11131W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 98.56 | 25.00 | [a] Entresto [NV]<br>[a] Omtralo [NM]<br>[a] Sacubitril/Valsartan Alphapharm [FY]<br>[a] SACUBITRIL/VALSARTAN-WGR [WG] | [a] MSN-SACUBITRIL/VALSARTAN [VM]<br>[a] Pharmacor Sacubitril/Valsartan [CR]<br>[a] Sacubitril/Valsartan Lupin 49/51 [GQ]<br>[a] Valtresto [TX] |

**sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56**

| 11122J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 98.56 | 25.00 | [a] Entresto [NV]<br>[a] Omtralo [NM]<br>[a] Sacubitril/Valsartan Alphapharm [FY]<br>[a] SACUBITRIL/VALSARTAN-WGR [WG] | [a] MSN-SACUBITRIL/VALSARTAN [VM]<br>[a] Pharmacor Sacubitril/Valsartan [CR]<br>[a] Sacubitril/Valsartan Lupin 97/103 [GQ]<br>[a] Valtresto [TX] |

## SACUBITRIL + VALSARTAN

**Authority Required (STREAMLINED)**

***18338***

Chronic heart failure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be symptomatic with NYHA classes II, III or IV, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- Patient must receive concomitant optimal standard chronic heart failure treatment, which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker: (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, **AND**
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; **OR**
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.

**sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56**

| 13570F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *186.18 | 25.00 | [a] Entresto [NV] | [a] MSN-SACUBITRIL/VALSARTAN [VM] |
| | | | | | | [a] Omtralo [NM] | [a] Pharmacor Sacubitril/Valsartan [CR] |
| | | | | | | [a] Sacubitril/Valsartan Alphapharm [FY] | [a] Sacubitril/Valsartan Lupin 24/26 [GQ] |
| | | | | | | [a] SACUBITRIL/VALSARTAN-WGR [WG] | [a] Valtresto [TX] |

**sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56**

| 13511D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *186.18 | 25.00 | [a] Entresto [NV] | [a] MSN-SACUBITRIL/VALSARTAN [VM] |
| | | | | | | [a] Omtralo [NM] | [a] Pharmacor Sacubitril/Valsartan [CR] |
| | | | | | | [a] Sacubitril/Valsartan Alphapharm [FY] | [a] Sacubitril/Valsartan Lupin 49/51 [GQ] |
| | | | | | | [a] SACUBITRIL/VALSARTAN-WGR [WG] | [a] Valtresto [TX] |

**sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56**

| 13445P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *186.18 | 25.00 | [a] Entresto [NV] | [a] MSN-SACUBITRIL/VALSARTAN [VM] |
| | | | | | | [a] Omtralo [NM] | [a] Pharmacor Sacubitril/Valsartan [CR] |
| | | | | | | [a] Sacubitril/Valsartan Alphapharm [FY] | [a] Sacubitril/Valsartan Lupin 97/103 [GQ] |
| | | | | | | [a] SACUBITRIL/VALSARTAN-WGR [WG] | [a] Valtresto [TX] |

# LIPID MODIFYING AGENTS

## LIPID MODIFYING AGENTS, PLAIN

### *HMG CoA reductase inhibitors*

## ATORVASTATIN

**atorvastatin 10 mg tablet, 30**

| 8213G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Atorvastatin [TX] | [a] ATOMED [DZ] |
| | | | | | | [a] Atorvachol [RF] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] ATORVASTATIN-WGR [WG] | [a] BTC Atorvastatin [BG] |
| | | | | | | [a] Lipitor [AS] | [a] Lorstat 10 [AF] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

**atorvastatin 20 mg tablet, 30**

| 8214H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.20 | 18.74 | [a] APO-Atorvastatin [TX] | [a] ATOMED [DZ] |
| | | | | | | [a] Atorvachol [RF] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] ATORVASTATIN-WGR [WG] | [a] BTC Atorvastatin [BG] |
| | | | | | | [a] Lipitor [AS] | [a] Lorstat 20 [AF] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

**atorvastatin 40 mg tablet, 30**

| 8215J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.05 | 19.59 | [a] APO-Atorvastatin [TX] | [a] ATOMED [DZ] |
| | | | | | | [a] Atorvachol [RF] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] ATORVASTATIN-WGR [WG] | [a] BTC Atorvastatin [BG] |
| | | | | | | [a] Lipitor [AS] | [a] Lorstat 40 [AF] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

**atorvastatin 80 mg tablet, 30**

| 8521L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Atorvastatin [TX] | [a] ATOMED [DZ] |
| | | | | | | [a] Atorvachol [RF] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] ATORVASTATIN-WGR [WG] | [a] BTC Atorvastatin [BG] |
| | | | | | | [a] Lipitor [AS] | [a] Lorstat 80 [AF] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

## ATORVASTATIN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**atorvastatin 10 mg tablet, 30**

| 13495G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APO-Atorvastatin [TX] | [a] ATOMED [DZ] |
| | | | | | | [a] Atorvachol [RF] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] ATORVASTATIN-WGR [WG] | [a] BTC Atorvastatin [BG] |
| | | | | | | [a] Lipitor [AS] | [a] Lorstat 10 [AF] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

**atorvastatin 20 mg tablet, 30**

| 13529C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *20.04 | 21.58 | [a] APO-Atorvastatin [TX] | [a] ATOMED [DZ] |
| | | | | | | [a] Atorvachol [RF] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] ATORVASTATIN-WGR [WG] | [a] BTC Atorvastatin [BG] |
| | | | | | | [a] Lipitor [AS] | [a] Lorstat 20 [AF] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

**atorvastatin 40 mg tablet, 30**

| 13468W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.74 | 23.28 | [a] APO-Atorvastatin [TX] | [a] ATOMED [DZ] |
| | | | | | | [a] Atorvachol [RF] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] ATORVASTATIN-WGR [WG] | [a] BTC Atorvastatin [BG] |
| | | | | | | [a] Lipitor [AS] | [a] Lorstat 40 [AF] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

**atorvastatin 80 mg tablet, 30**

| 13374X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Atorvastatin [TX] | [a] ATOMED [DZ] |
| | | | | | | [a] Atorvachol [RF] | [a] Atorvastatin SZ [HX] |
| | | | | | | [a] ATORVASTATIN-WGR [WG] | [a] BTC Atorvastatin [BG] |
| | | | | | | [a] Lipitor [AS] | [a] Lorstat 80 [AF] |
| | | | | | | [a] Pharmacor Atorvastatin [CR] | [a] Trovas [RA] |

## PRAVASTATIN

### pravastatin sodium 10 mg tablet, 30

| 2833D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APX-Pravastatin [TY] | [a] Lipostat 10 [RF] |
| | | | | | | [a] Pravastatin Sandoz [SZ] | [a] PRAVASTATIN-WGR [WG] |
| | | | [B]2.75 | 19.85 | 18.64 | [a] Cholstat 10 [AF] | |
| | | | [B]4.69 | 21.79 | 18.64 | [a] Pravachol [RW] | |

### pravastatin sodium 20 mg tablet, 30

| 2834E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.37 | 18.91 | [a] APX-Pravastatin [TY] | [a] Cholstat 20 [AF] |
| | | | | | | [a] Lipostat 20 [RF] | [a] Pravastatin Sandoz [SZ] |
| | | | | | | [a] PRAVASTATIN-WGR [WG] | |
| | | | [B]4.71 | 22.08 | 18.91 | [a] Pravachol [RW] | |

### pravastatin sodium 40 mg tablet, 30

| 8197K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.13 | 19.67 | [a] APX-Pravastatin [TY] | [a] Cholstat 40 [AF] |
| | | | | | | [a] Lipostat 40 [RF] | [a] Pravastatin Sandoz [SZ] |
| | | | | | | [a] PRAVASTATIN-WGR [WG] | |
| | | | [B]4.75 | 22.88 | 19.67 | [a] Pravachol [RW] | |

### pravastatin sodium 80 mg tablet, 30

| 8829Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.03 | 21.57 | [a] APX-Pravastatin [TY] | [a] Lipostat 80 [RF] |
| | | | [B]4.99 | 25.02 | 21.57 | [a] Pravachol [RW] | |

## PRAVASTATIN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### pravastatin sodium 10 mg tablet, 30

| 13496H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APX-Pravastatin [TY] | [a] Lipostat 10 [RF] |
| | | | | | | [a] Pravastatin Sandoz [SZ] | [a] PRAVASTATIN-WGR [WG] |
| | | | [B]5.50 | 25.34 | 21.38 | [a] Cholstat 10 [AF] | |
| | | | [B]9.38 | 29.22 | 21.38 | [a] Pravachol [RW] | |

### pravastatin sodium 20 mg tablet, 30

| 13497J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *20.38 | 21.92 | [a] APX-Pravastatin [TY] | [a] Cholstat 20 [AF] |
| | | | | | | [a] Lipostat 20 [RF] | [a] Pravastatin Sandoz [SZ] |
| | | | | | | [a] PRAVASTATIN-WGR [WG] | |
| | | | [B]9.42 | 29.80 | 21.92 | [a] Pravachol [RW] | |

### pravastatin sodium 40 mg tablet, 30

| 13432Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.90 | 23.44 | [a] APX-Pravastatin [TY] | [a] Cholstat 40 [AF] |
| | | | | | | [a] Lipostat 40 [RF] | [a] Pravastatin Sandoz [SZ] |
| | | | | | | [a] PRAVASTATIN-WGR [WG] | |
| | | | [B]9.50 | 31.40 | 23.44 | [a] Pravachol [RW] | |

### pravastatin sodium 80 mg tablet, 30

| 13527Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *25.70 | 25.00 | [a] APX-Pravastatin [TY] | [a] Lipostat 80 [RF] |
| | | | [B]9.98 | *35.68 | 25.00 | [a] Pravachol [RW] | |

## ROSUVASTATIN

### rosuvastatin 5 mg tablet, 30

| 2606E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-ROSUVASTATIN [TX] | [a] APX-Rosuvastatin [TY] |
| | | | | | | [a] Blooms Rosuvastatin [BG] | [a] Cavstat [AF] |
| | | | | | | [a] Crosuva 5 [RW] | [a] Pharmacor Rosuvastatin 5 [CR] |
| | | | | | | [a] Rosuvastatin Lupin [GQ] | [a] Rosuvastatin RBX [RA] |
| | | | | | | [a] Rosuvastatin Sandoz [SZ] | [a] ROSUVASTATIN-WGR [WG] |
| | | | [B]4.68 | 21.78 | 18.64 | [a] Crestor [FK] | |

### rosuvastatin 10 mg tablet, 30

| 2628H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APO-ROSUVASTATIN [TX] | [a] APX-Rosuvastatin [TY] |
| | | | | | | [a] Blooms Rosuvastatin [BG] | [a] Cavstat [AF] |
| | | | | | | [a] Crosuva 10 [RW] | [a] Pharmacor Rosuvastatin 10 [CR] |
| | | | | | | [a] Rosuvastatin Lupin [GQ] | [a] Rosuvastatin RBX [RA] |
| | | | | | | [a] Rosuvastatin Sandoz [SZ] | [a] ROSUVASTATIN-WGR [WG] |
| | | | [B]4.70 | 22.80 | 19.64 | [a] Crestor [FK] | |

### rosuvastatin 20 mg tablet, 30

| 2574L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.15 | 19.69 | [a] APO-ROSUVASTATIN [TX] | [a] APX-Rosuvastatin [TY] |
| | | | | | | [a] Blooms Rosuvastatin [BG] | [a] Cavstat [AF] |
| | | | | | | [a] Crosuva 20 [RW] | [a] Pharmacor Rosuvastatin 20 [CR] |
| | | | | | | [a] Rosuvastatin Lupin [GQ] | [a] Rosuvastatin RBX [RA] |
| | | | | | | [a] Rosuvastatin Sandoz [SZ] | [a] ROSUVASTATIN-WGR [WG] |
| | | | [B]4.71 | 22.86 | 19.69 | [a] Crestor [FK] | |

### rosuvastatin 40 mg tablet, 30

| 2594M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.66 | 21.20 | [a] APO-ROSUVASTATIN [TX] | [a] APX-Rosuvastatin [TY] |
| | | | | | | [a] Blooms Rosuvastatin [BG] | [a] Cavstat [AF] |
| | | | | | | [a] Crosuva 40 [RW] | [a] Pharmacor Rosuvastatin 40 [CR] |
| | | | | | | [a] Rosuvastatin Lupin [GQ] | [a] Rosuvastatin RBX [RA] |
| | | | | | | [a] Rosuvastatin Sandoz [SZ] | [a] ROSUVASTATIN-WGR [WG] |
| | | | [B]4.76 | 24.42 | 21.20 | [a] Crestor [FK] | |

## ROSUVASTATIN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### rosuvastatin 5 mg tablet, 30

| 13406N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APO-ROSUVASTATIN [TX] | [a] APX-Rosuvastatin [TY] |
| | | | | | | [a] Blooms Rosuvastatin [BG] | [a] Cavstat [AF] |
| | | | | | | [a] Crosuva 5 [RW] | [a] Pharmacor Rosuvastatin 5 [CR] |
| | | | | | | [a] Rosuvastatin Lupin [GQ] | [a] Rosuvastatin RBX [RA] |
| | | | | | | [a] Rosuvastatin Sandoz [SZ] | [a] ROSUVASTATIN-WGR [WG] |
| | | | [B]9.36 | 29.20 | 21.38 | [a] Crestor [FK] | |

### rosuvastatin 10 mg tablet, 30

| 13586C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] APO-ROSUVASTATIN [TX] | [a] APX-Rosuvastatin [TY] |
| | | | | | | [a] Blooms Rosuvastatin [BG] | [a] Cavstat [AF] |

| 13586C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Crosuva 10 [RW] | [a] Pharmacor Rosuvastatin 10 [CR] |
| | | | | | | [a] Rosuvastatin Lupin [GQ] | [a] Rosuvastatin RBX [RA] |
| | | | | | | [a] Rosuvastatin Sandoz [SZ] | [a] ROSUVASTATIN-WGR [WG] |
| | | | [B]9.40 | 31.24 | 23.38 | [a] Crestor [FK] | |

**rosuvastatin 20 mg tablet, 30**

| 13588E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.94 | 23.48 | [a] APO-ROSUVASTATIN [TX] | [a] APX-Rosuvastatin [TY] |
| | | | | | | [a] Blooms Rosuvastatin [BG] | [a] Cavstat [AF] |
| | | | | | | [a] Crosuva 20 [RW] | [a] Pharmacor Rosuvastatin 20 [CR] |
| | | | | | | [a] Rosuvastatin Lupin [GQ] | [a] Rosuvastatin RBX [RA] |
| | | | | | | [a] Rosuvastatin Sandoz [SZ] | [a] ROSUVASTATIN-WGR [WG] |
| | | | [B]9.42 | 31.36 | 23.48 | [a] Crestor [FK] | |

**rosuvastatin 40 mg tablet, 30**

| 13589F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.96 | 25.00 | [a] APO-ROSUVASTATIN [TX] | [a] APX-Rosuvastatin [TY] |
| | | | | | | [a] Blooms Rosuvastatin [BG] | [a] Cavstat [AF] |
| | | | | | | [a] Crosuva 40 [RW] | [a] Pharmacor Rosuvastatin 40 [CR] |
| | | | | | | [a] Rosuvastatin Lupin [GQ] | [a] Rosuvastatin RBX [RA] |
| | | | | | | [a] Rosuvastatin Sandoz [SZ] | [a] ROSUVASTATIN-WGR [WG] |
| | | | [B]9.52 | 34.48 | 25.00 | [a] Crestor [FK] | |

## SIMVASTATIN

**simvastatin 5 mg tablet, 30**

| 2013Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] Simvastatin Sandoz [SZ] | [a] Zimstat [AF] |

**simvastatin 10 mg tablet, 30**

| 2011W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Simvastatin [TX] | [a] Simvar 10 [RW] |
| | | | | | | [a] Simvastatin Sandoz [SZ] | [a] SIMVASTATIN-WGR [WG] |
| | | | | | | [a] Zimstat [AF] | |

**simvastatin 20 mg tablet, 30**

| 2012X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Simvastatin [TX] | [a] Simvar 20 [RW] |
| | | | | | | [a] Simvastatin Sandoz [SZ] | [a] SIMVASTATIN-WGR [WG] |
| | | | | | | [a] Zimstat [AF] | |
| | | | [B]8.89 | 25.99 | 18.64 | [a] Lipex 20 [AL] | |
| | | | [B]8.89 | 25.99 | 18.64 | [a] Zocor [MQ] | |

**simvastatin 40 mg tablet, 30**

| 8173E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.27 | 18.81 | [a] APO-Simvastatin [TX] | [a] Simvar 40 [RW] |
| | | | | | | [a] Simvastatin Sandoz [SZ] | [a] SIMVASTATIN-WGR [WG] |
| | | | | | | [a] Zimstat [AF] | |
| | | | [B]8.84 | 26.11 | 18.81 | [a] Lipex 40 [AL] | |
| | | | [B]8.84 | 26.11 | 18.81 | [a] Zocor [MQ] | |

**simvastatin 80 mg tablet, 30**

| 8313M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APO-Simvastatin [TX] | [a] Simvar 80 [RW] |
| | | | | | | [a] Simvastatin Sandoz [SZ] | [a] SIMVASTATIN-WGR [WG] |
| | | | | | | [a] Zimstat [AF] | |

## SIMVASTATIN

**Restricted benefit**

***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**simvastatin 5 mg tablet, 30**

| 13559P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Simvastatin Sandoz [SZ] | [a] Zimstat [AF] |

**simvastatin 10 mg tablet, 30**

| 13528B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APO-Simvastatin [TX] | [a] Simvar 10 [RW] |
| | | | | | | [a] Simvastatin Sandoz [SZ] | [a] SIMVASTATIN-WGR [WG] |
| | | | | | | [a] Zimstat [AF] | |

**simvastatin 20 mg tablet, 30**

| 13373W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APO-Simvastatin [TX] | [a] Simvar 20 [RW] |
| | | | | | | [a] Simvastatin Sandoz [SZ] | [a] SIMVASTATIN-WGR [WG] |
| | | | | | | [a] Zimstat [AF] | |
| | | | [B]17.78 | 37.62 | 21.38 | [a] Lipex 20 [AL] | |
| | | | [B]17.78 | 37.62 | 21.38 | [a] Zocor [MQ] | |

**simvastatin 40 mg tablet, 30**

| 13471B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *20.18 | 21.72 | [a] APO-Simvastatin [TX] | [a] Simvar 40 [RW] |
| | | | | | | [a] Simvastatin Sandoz [SZ] | [a] SIMVASTATIN-WGR [WG] |
| | | | | | | [a] Zimstat [AF] | |
| | | | [B]17.68 | 37.86 | 21.72 | [a] Lipex 40 [AL] | |
| | | | [B]17.68 | 37.86 | 21.72 | [a] Zocor [MQ] | |

**simvastatin 80 mg tablet, 30**

| 13498K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] APO-Simvastatin [TX] | [a] Simvar 80 [RW] |
| | | | | | | [a] Simvastatin Sandoz [SZ] | [a] SIMVASTATIN-WGR [WG] |
| | | | | | | [a] Zimstat [AF] | |

## *Fibrates*

### FENOFIBRATE

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**fenofibrate 48 mg tablet, 60**

| 9022W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Fenofibrate [TX] | [a] ARX-FENOFIBRATE [TY] |
| | | | | | | [a] Fenofibrate Lupin [GQ] | [a] FENOFIBRATE RBX [RA] |
| | | | | | | [a] Fenofibrate Viatris [AL] | [a] FENOFIBRATE-WGR [WG] |
| | | | | | | [a] Lipidil [GO] | |

**fenofibrate 145 mg tablet, 30**

| 9023X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.52 | 22.06 | [a] APO-Fenofibrate [TX] | [a] ARX-FENOFIBRATE [TY] |
| | | | | | | [a] BTC Fenofibrate [BG] | [a] Fenocol [XT] |
| | | | | | | [a] Fenofibrate Cipla [LR] | [a] Fenofibrate Lupin [GQ] |
| | | | | | | [a] FENOFIBRATE RBX [RA] | [a] Fenofibrate Sandoz [SZ] |
| | | | | | | [a] Fenofibrate Viatris [AL] | [a] FENOFIBRATE-WGR [WG] |
| | | | | | | [a] Lipidil [GO] | |

### FENOFIBRATE

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**fenofibrate 48 mg tablet, 60**

| 13469X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Fenofibrate [TX] | [a] ARX-FENOFIBRATE [TY] |
| | | | | | | [a] Fenofibrate Lupin [GQ] | [a] FENOFIBRATE RBX [RA] |
| | | | | | | [a] Fenofibrate Viatris [AL] | [a] FENOFIBRATE-WGR [WG] |
| | | | | | | [a] Lipidil [GO] | |

**fenofibrate 145 mg tablet, 30**

| 13587D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *26.68 | 25.00 | [a] APO-Fenofibrate [TX] | [a] ARX-FENOFIBRATE [TY] |
| | | | | | | [a] BTC Fenofibrate [BG] | [a] Fenocol [XT] |
| | | | | | | [a] Fenofibrate Cipla [LR] | [a] Fenofibrate Lupin [GQ] |
| | | | | | | [a] FENOFIBRATE RBX [RA] | [a] Fenofibrate Sandoz [SZ] |
| | | | | | | [a] Fenofibrate Viatris [AL] | [a] FENOFIBRATE-WGR [WG] |
| | | | | | | [a] Lipidil [GO] | |

## GEMFIBROZIL

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**gemfibrozil 600 mg tablet, 60**

| 1453L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 23.97 | 25.00 | [a] Ausgem [RW] | [a] Lipigem [AF] |

## GEMFIBROZIL

**Note** The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**gemfibrozil 600 mg tablet, 60**

| 13618R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *33.58 | 25.00 | [a] Ausgem [RW] | [a] Lipigem [AF] |

### *Bile acid sequestrants*

## COLESTYRAMINE

**colestyramine 4 g powder for oral liquid, 50 sachets**

| 2967E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *95.72 | 25.00 | Questran Lite [GO] |

## COLESTYRAMINE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**colestyramine 4 g powder for oral liquid, 50 sachets**

| 14477Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *180.20 | 25.00 | Questran Lite [GO] |

### *Other lipid modifying agents*

## EVOLOCUMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17313***

Familial homozygous hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; **OR**
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; **OR**
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; **OR**
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information.

**Treatment criteria:**

- Must be treated by a specialist physician; **OR**
- Must be treated by an authorised prescriber in consultation with a specialist physician.

The qualifying LDL cholesterol level following at least 12 consecutive weeks of treatment with a statin (unless treatment with a statin is contraindicated or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

The following must be documented in the patient's medical records:

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial homozygous hypercholesterolaemia

One of the following must be documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

**evolocumab 140 mg/mL injection, 1 mL pen device**

| 10958R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *633.60 | 25.00 | Repatha [AN] |

## EVOLOCUMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17402***

Familial homozygous hypercholesterolaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

**evolocumab 140 mg/mL injection, 1 mL pen device**

| 11977J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *633.60 | 25.00 | Repatha [AN] |

## EVOLOCUMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***19418***

Familial homozygous hypercholesterolaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

### evolocumab 140 mg/mL injection, 1 mL pen device

15599B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 6 | 5 | 0.00 | *1,257.84 | 25.00 | Repatha [AN] |

NP

## EVOLOCUMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16294***

Familial heterozygous hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; **OR**
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; **OR**
- Patient must have an LDL cholesterol level in excess of 5 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; **OR**
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; **OR**
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; **OR**
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication.

**Treatment criteria:**

- Must be treated by a specialist physician; **OR**
- Must be treated by an authorised prescriber in consultation with a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

The following must be documented in the patient's medical records:

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

**Authority Required (STREAMLINED)**

***16351***

Non-familial hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have symptomatic atherosclerotic cardiovascular disease, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre, **AND**
- Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); **OR**
- Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; **OR**
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; **OR**
- Patient must have diabetes mellitus with microalbuminuria; **OR**
- Patient must have diabetes mellitus and be aged 60 years or more; **OR**
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; **OR**
- Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; **OR**
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; **OR**
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; **OR**
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication.

**Treatment criteria:**

- Must be treated by a specialist physician; **OR**
- Must be treated by an authorised prescriber in consultation with a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or
(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).
The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.
A clinically important product-related adverse event is defined as follows:
(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.
If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.
In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.
One of the following must be documented in the patient's medical records regarding prior statin treatment:
(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or
(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or
(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.
One or more of the following must be documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:
(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or
(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or
(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or
(iv) diabetes mellitus with microalbuminuria; or
(v) diabetes mellitus and age 60 years of more; or
(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or
(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher
Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

### evolocumab 140 mg/mL injection, 1 mL pen device

11484K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *425.52 | 25.00 | Repatha [AN] |

NP

## EVOLOCUMAB

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16336***

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**Authority Required (STREAMLINED)**

***16350***

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**evolocumab 140 mg/mL injection, 1 mL pen device**

| 11985T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *425.52 | 25.00 | Repatha [AN] |

## EVOLOCUMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***19523***

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**Authority Required (STREAMLINED)**

***19514***

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**evolocumab 140 mg/mL injection, 1 mL pen device**

| 15592P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *841.68 | 25.00 | Repatha [AN] |

## EZETIMIBE

**ezetimibe 10 mg tablet, 30**

| 8757X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.95 | 20.49 | [a] APO-Ezetimibe [TX] | [a] ARX-EZETIMIBE [XT] |
| | | | | | | [a] BTC Ezetimibe [BG] | [a] EZEMICHOL [RW] |
| | | | | | | [a] Ezetimibe GH [GQ] | [a] Ezetimibe Sandoz [SZ] |
| | | | | | | [a] Ezetimibe Viatris [MQ] | [a] EZETIMIBE-WGR [WG] |
| | | | | | | [a] Pharmacor Ezetimibe 10 [CR] | [a] Zient 10mg [AF] |
| | | | [B]3.24 | 22.19 | 20.49 | [a] Ezetrol [AL] | |

## EZETIMIBE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ezetimibe 10 mg tablet, 30**

| 13440J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *23.54 | 25.00 | [a] APO-Ezetimibe [TX] | [a] ARX-EZETIMIBE [XT] |
| | | | | | | [a] BTC Ezetimibe [BG] | [a] EZEMICHOL [RW] |
| | | | | | | [a] Ezetimibe GH [GQ] | [a] Ezetimibe Sandoz [SZ] |
| | | | | | | [a] Ezetimibe Viatris [MQ] | [a] EZETIMIBE-WGR [WG] |
| | | | | | | [a] Pharmacor Ezetimibe 10 [CR] | [a] Zient 10mg [AF] |
| | | | [B]6.48 | 30.02 | 25.00 | [a] Ezetrol [AL] | |

## ICOSAPENT ETHYL

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15889***

Established atherosclerotic cardiovascular disease with hypertriglyceridaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have at least one of (i) coronary artery disease, (ii) cerebrovascular or carotid disease, (iii) peripheral arterial disease, **AND**
- Patient must be treated with a stable dose of a HMG CoA reductase inhibitor (statin) to achieve target secondary prevention LDL-c levels for at least 12 consecutive weeks; **OR**
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment; **OR**
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have LDL cholesterol level between 1.0 millimoles per litre and 2.6 millimoles per litre; **OR**
- Patient must have a non-HDL cholesterol between 1.5 millimoles per litre and 3.5 millimoles per litre if LDL cannot be measured/detected, **AND**
- Patient must have fasting triglyceride level between 1.7 millimoles per litre and 5.6 millimoles per litre.

The qualifying fasting triglyceride level and LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, dietary therapy and exercise should be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Atherosclerotic cardiovascular disease is defined as:

(i) Documented coronary artery disease (CAD); one or more of the following primary criteria must have been satisfied:

a) Documented multi-vessel CAD (at least 50% stenosis in at least two major epicardial coronary arteries, with or without antecedent revascularisation).

b) Documented prior MI.

c) Hospitalisation for high-risk non-ST-segment elevation acute coronary syndrome, with objective evidence of ischemia: ST-segment deviation or biomarker positivity.

(ii) Documented cerebrovascular or carotid disease; one of the following primary criteria must have been satisfied:
a) Documented prior ischemic stroke.
b) Symptomatic carotid artery disease with at least 50% carotid arterial stenosis.
c) Asymptomatic carotid artery disease with at least 70% carotid arterial stenosis per angiography or duplex ultrasound.
d) History of carotid revascularisation (catheter-based or surgical).
(iii) Documented peripheral arterial disease; one or more of the following primary criteria must have been satisfied:
a) Ankle brachial index (ABI) less than 0.9 with symptoms of intermittent claudication.
b) History of aorto-iliac or peripheral arterial intervention (catheter-based or surgical).

**Authority Required (STREAMLINED)**

***15927***

Established atherosclerotic cardiovascular disease with hypertriglyceridaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The treatment must be co-administered with a HMG CoA reductase inhibitor (statin), unless the patient is contraindicated to statins or has developed statin related adverse events necessitating withdrawal of statin treatment.

### Icosapent ethyl 998 mg capsule, 120

14617H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 150.64 | 25.00 | Vazkepa [CS] |

## INCLISIRAN

**Note** Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab.

**Note** Authority applications for increased repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16320***

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein coverase subtilisin kexin type 9 (PSCK9) for this PBS indication

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**Authority Required (STREAMLINED)**

***16356***

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein coverase subtilisin kexin type 9 (PSCK9) for this PBS indication

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

### inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe

14087K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 1,853.35 | 25.00 | Leqvio [NV] |

NP

## INCLISIRAN

**Note** Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16295***

Familial heterozygous hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; **OR**
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; **OR**
- Patient must have an LDL cholesterol level in excess of 5 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; **OR**
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; **OR**
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; **OR**
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

**Treatment criteria:**

- Must be treated by a specialist physician; **OR**
- Must be treated by an authorised prescriber in consultation with a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

The following must be documented in the patient's medical records:

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

**Authority Required (STREAMLINED)**

***16331***

Non-familial hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have symptomatic atherosclerotic cardiovascular disease, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre, **AND**
- Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); **OR**
- Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; **OR**
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; **OR**
- Patient must have diabetes mellitus with microalbuminuria; **OR**
- Patient must have diabetes mellitus and be aged 60 years or more; **OR**
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; **OR**
- Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; **OR**
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; **OR**
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; **OR**
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

**Treatment criteria:**

- Must be treated by a specialist physician; **OR**
- Must be treated by an authorised prescriber in consultation with a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or

(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or

(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or

(iv) diabetes mellitus with microalbuminuria; or

(v) diabetes mellitus and age 60 years or more; or

(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or

(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher.

Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.

**inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe**

| 14101E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 1,853.35 | 25.00 | Leqvio [NV] |

## LIPID MODIFYING AGENTS, COMBINATIONS

### *Combinations of various lipid modifying agents*

## EZETIMIBE (&) ROSUVASTATIN

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 5 mg tablet [30], 60**

| 10204C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 25.57 | 25.00 | [a] Ezalo Composite Pack 10mg+5mg [AF] | [a] Ezetimibe - Rosuvastatin Sandoz 10 mg/5 mg [SZ] |
| | | | [B]2.79 | 28.36 | 25.00 | [a] Rosuzet Composite Pack [AL] | |

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60**

| 10208G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 26.92 | 25.00 | [a] Ezalo Composite Pack 10mg+10mg [AF] | [a] Ezetimibe - Rosuvastatin Sandoz 10 mg/10 mg [SZ] |
| | | | | | | [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR] | |
| | | | [B]2.89 | 29.81 | 25.00 | [a] Rosuzet Composite Pack [AL] | |

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60**

| 10201X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 28.84 | 25.00 | [a] Ezalo Composite Pack 10mg+20mg [AF] | [a] Ezetimibe - Rosuvastatin Sandoz 10 mg/20 mg [SZ] |
| | | | | | | [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR] | |
| | | | [B]2.89 | 31.73 | 25.00 | [a] Rosuzet Composite Pack [AL] | |

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60**

| 10207F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 28.53 | 25.00 | [a] Ezalo Composite Pack 10mg+40mg [AF] | [a] Ezetimibe - Rosuvastatin Sandoz 10 mg/40 mg [SZ] |
| | | | | | | [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR] | |
| | | | [B]3.00 | 31.53 | 25.00 | [a] Rosuzet Composite Pack [AL] | |

## EZETIMIBE (&) ROSUVASTATIN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 5 mg tablet [30], 60**

| 13629H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *36.78 | 25.00 | [a] Ezalo Composite Pack 10mg+5mg [AF] | [a] Ezetimibe - Rosuvastatin Sandoz 10 mg/5 mg [SZ] |
| | | | [B]5.58 | *42.36 | 25.00 | [a] Rosuzet Composite Pack [AL] | |

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60**

| 13569E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *39.48 | 25.00 | [a] Ezalo Composite Pack 10mg+10mg [AF] | [a] Ezetimibe - Rosuvastatin Sandoz 10 mg/10 mg [SZ] |
| | | | | | | [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR] | |
| | | | [B]5.78 | 45.26 | 25.00 | [a] Rosuzet Composite Pack [AL] | |

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60**

| 13480L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *43.32 | 25.00 | [a] Ezalo Composite Pack 10mg+20mg [AF] | [a] Ezetimibe - Rosuvastatin Sandoz 10 mg/20 mg [SZ] |
| | | | | | | [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR] | |
| | | | [B]5.78 | 49.10 | 25.00 | [a] Rosuzet Composite Pack [AL] | |

**ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60**

| 13537L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *42.70 | 25.00 | [a] Ezalo Composite Pack 10mg+40mg [AF] | [a] Ezetimibe - Rosuvastatin Sandoz 10 mg/40 mg [SZ] |
| | | | | | | [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [CR] | |
| | | | [B]6.00 | 48.70 | 25.00 | [a] Rosuzet Composite Pack [AL] | |

## EZETIMIBE + ATORVASTATIN

**ezetimibe 10 mg + atorvastatin 10 mg tablet, 30**

| 10392Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 22.67 | 24.21 | [a] Atozet [AF] | [a] Ezetast [XT] |
| | | | | | | [a] Ezetimibe/Atorvastatin GH 10/10 [GQ] | |

**ezetimibe 10 mg + atorvastatin 20 mg tablet, 30**

| 10393B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 23.22 | 24.76 | [a] Atozet [AF] | [a] Ezetast [XT] |
| | | | | | | [a] Ezetimibe/Atorvastatin GH 10/20 [GQ] | |

**ezetimibe 10 mg + atorvastatin 40 mg tablet, 30**

| 10377E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 25.13 | 25.00 | [a] Ezetast [XT] | [a] Ezetimibe/Atorvastatin GH 10/40 [GQ] |
| | | | [B]2.16 | 27.29 | 25.00 | [a] Atozet [AF] | |

**ezetimibe 10 mg + atorvastatin 80 mg tablet, 30**

| 10376D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 27.87 | 25.00 | [a] Ezetast [XT] | [a] Ezetimibe/Atorvastatin GH 10/80 [GQ] |
| | | | [B]2.91 | 30.78 | 25.00 | [a] Atozet [AF] | |

## EZETIMIBE + ATORVASTATIN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ezetimibe 10 mg + atorvastatin 10 mg tablet, 30**

| 13539N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *30.98 | 25.00 | [a] Atozet [AF] | [a] Ezetast [XT] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13539N | | | | | | [a] Ezetimibe/Atorvastatin GH 10/10 [GQ] | |

**ezetimibe 10 mg + atorvastatin 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13622Y | | | | | | | |
| NP | 2 | 5 | 0.00 | *32.08 | 25.00 | [a] Atozet [AF] | [a] Ezetast [XT] |
| | | | | | | [a] Ezetimibe/Atorvastatin GH 10/20 [GQ] | |

**ezetimibe 10 mg + atorvastatin 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13416D | | | | | | | |
| NP | 2 | 5 | 0.00 | *35.90 | 25.00 | [a] Ezetast [XT] | [a] Ezetimibe/Atorvastatin GH 10/40 [GQ] |
| | | | [B]4.32 | *40.22 | 25.00 | [a] Atozet [AF] | |

**ezetimibe 10 mg + atorvastatin 80 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13538M | | | | | | | |
| NP | 2 | 5 | 0.00 | *41.38 | 25.00 | [a] Ezetast [XT] | [a] Ezetimibe/Atorvastatin GH 10/80 [GQ] |
| | | | [B]5.82 | *47.20 | 25.00 | [a] Atozet [AF] | |

## EZETIMIBE + SIMVASTATIN

**ezetimibe 10 mg + simvastatin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9483D | | | | | | | |
| NP | 1 | 5 | 0.00 | 20.83 | 22.37 | [a] APO-Ezetimibe/Simvastatin 10/10 [TX] | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] |
| | | | | | | [a] EZETIMIBE/SIMVASTATIN-WGR 10/10 [WG] | [a] EZETORIN [RW] |
| | | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/10 [CR] | [a] Zimybe 10/10 [MQ] |
| | | | [B]1.94 | 22.77 | 22.37 | [a] Vytorin [AL] | |

**ezetimibe 10 mg + simvastatin 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9484E | | | | | | | |
| NP | 1 | 5 | 0.00 | 21.15 | 22.69 | [a] APO-Ezetimibe/Simvastatin 10/20 [TX] | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] |
| | | | | | | [a] EZETIMIBE/SIMVASTATIN-WGR 10/20 [WG] | [a] EZETORIN [RW] |
| | | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/20 [CR] | [a] Zimybe 10/20 [MQ] |
| | | | [B]1.94 | 23.09 | 22.69 | [a] Vytorin [AL] | |

**ezetimibe 10 mg + simvastatin 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8881K | | | | | | | |
| NP | 1 | 5 | 0.00 | 21.61 | 23.15 | [a] APO-Ezetimibe/Simvastatin 10/40 [TX] | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] |
| | | | | | | [a] EZETIMIBE/SIMVASTATIN-WGR 10/40 [WG] | [a] EZETORIN [RW] |
| | | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/40 [CR] | [a] Zimybe 10/40 [MQ] |
| | | | [B]2.91 | 24.52 | 23.15 | [a] Vytorin [AL] | |

**ezetimibe 10 mg + simvastatin 80 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8882L | | | | | | | |
| NP | 1 | 5 | 0.00 | 22.25 | 23.79 | [a] APO-Ezetimibe/Simvastatin 10/80 [TX] | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] |
| | | | | | | [a] EZETIMIBE/SIMVASTATIN-WGR 10/80 [WG] | [a] EZETORIN [RW] |
| | | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/80 [CR] | [a] Zimybe 10/80 [MQ] |
| | | | [B]2.91 | 25.16 | 23.79 | [a] Vytorin [AL] | |

## EZETIMIBE + SIMVASTATIN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ezetimibe 10 mg + simvastatin 10 mg tablet, 30**

| 13385L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *27.30 | 25.00 | [a] APO-Ezetimibe/Simvastatin 10/10 [TX] | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] |
| | | | | | | [a] EZETIMIBE/SIMVASTATIN-WGR 10/10 [WG] | [a] EZETORIN [RW] |
| | | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/10 [CR] | [a] Zimybe 10/10 [MQ] |
| | | | [B]3.88 | 31.18 | 25.00 | [a] Vytorin [AL] | |

**ezetimibe 10 mg + simvastatin 20 mg tablet, 30**

| 13442L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *27.94 | 25.00 | [a] APO-Ezetimibe/Simvastatin 10/20 [TX] | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] |
| | | | | | | [a] EZETIMIBE/SIMVASTATIN-WGR 10/20 [WG] | [a] EZETORIN [RW] |
| | | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/20 [CR] | [a] Zimybe 10/20 [MQ] |
| | | | [B]3.88 | 31.82 | 25.00 | [a] Vytorin [AL] | |

**ezetimibe 10 mg + simvastatin 40 mg tablet, 30**

| 13535J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *28.86 | 25.00 | [a] APO-Ezetimibe/Simvastatin 10/40 [TX] | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] |
| | | | | | | [a] EZETIMIBE/SIMVASTATIN-WGR 10/40 [WG] | [a] EZETORIN [RW] |
| | | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/40 [CR] | [a] Zimybe 10/40 [MQ] |
| | | | [B]5.82 | 34.68 | 25.00 | [a] Vytorin [AL] | |

**ezetimibe 10 mg + simvastatin 80 mg tablet, 30**

| 13595M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *30.14 | 25.00 | [a] APO-Ezetimibe/Simvastatin 10/80 [TX] | [a] EZETIMIBE/SIMVASTATIN SANDOZ [SZ] |
| | | | | | | [a] EZETIMIBE/SIMVASTATIN-WGR 10/80 [WG] | [a] EZETORIN [RW] |
| | | | | | | [a] Pharmacor Ezetimibe Simvastatin 10/80 [CR] | [a] Zimybe 10/80 [MQ] |
| | | | [B]5.82 | 35.96 | 25.00 | [a] Vytorin [AL] | |

***Lipid modifying agents in combination with other drugs***

## AMLODIPINE + ATORVASTATIN

**amlodipine 5 mg + atorvastatin 10 mg tablet, 30**

| 9049G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.35 | 18.89 | Cadivast 5/10 [AF] |

**amlodipine 5 mg + atorvastatin 20 mg tablet, 30**

| 9050H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.03 | 19.57 | Cadivast 5/20 [AF] |

**amlodipine 5 mg + atorvastatin 40 mg tablet, 30**

| 9051J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.38 | 19.92 | [a] Cadivast 5/40 [AF] | [a] Caduet 5/40 [AS] |

**amlodipine 5 mg + atorvastatin 80 mg tablet, 30**

| 9052K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.65 | 21.19 | [a] Cadivast 5/80 [AF] | [a] Caduet 5/80 [AS] |

**amlodipine 10 mg + atorvastatin 10 mg tablet, 30**

| 9053L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.99 | 19.53 | [a] Cadivast 10/10 [AF] | [a] Caduet 10/10 [AS] |

**amlodipine 10 mg + atorvastatin 20 mg tablet, 30**

| 9054M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.17 | 19.71 | [a] Cadivast 10/20 [AF] | [a] Caduet 10/20 [AS] |

**amlodipine 10 mg + atorvastatin 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9055N NP | 1 | 5 | 0.00 | 19.02 | 20.56 | [a] Cadivast 10/40 [AF] | [a] Caduet 10/40 [AS] |

**amlodipine 10 mg + atorvastatin 80 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9056P NP | 1 | 5 | 0.00 | 20.29 | 21.83 | [a] Cadivast 10/80 [AF] | [a] Caduet 10/80 [AS] |

## AMLODIPINE + ATORVASTATIN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**amlodipine 5 mg + atorvastatin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13596N NP | 2 | 5 | 0.00 | *20.34 | 21.88 | Cadivast 5/10 [AF] |

**amlodipine 5 mg + atorvastatin 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13567C NP | 2 | 5 | 0.00 | *21.70 | 23.24 | Cadivast 5/20 [AF] |

**amlodipine 5 mg + atorvastatin 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13415C NP | 2 | 5 | 0.00 | *22.40 | 23.94 | [a] Cadivast 5/40 [AF] | [a] Caduet 5/40 [AS] |

**amlodipine 5 mg + atorvastatin 80 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13597P NP | 2 | 5 | 0.00 | *24.94 | 25.00 | [a] Cadivast 5/80 [AF] | [a] Caduet 5/80 [AS] |

**amlodipine 10 mg + atorvastatin 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13479K NP | 2 | 5 | 0.00 | *21.62 | 23.16 | [a] Cadivast 10/10 [AF] | [a] Caduet 10/10 [AS] |

**amlodipine 10 mg + atorvastatin 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13384K NP | 2 | 5 | 0.00 | *21.98 | 23.52 | [a] Cadivast 10/20 [AF] | [a] Caduet 10/20 [AS] |

**amlodipine 10 mg + atorvastatin 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13536K NP | 2 | 5 | 0.00 | *23.68 | 25.00 | [a] Cadivast 10/40 [AF] | [a] Caduet 10/40 [AS] |

**amlodipine 10 mg + atorvastatin 80 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13963X NP | 2 | 5 | 0.00 | *26.22 | 25.00 | [a] Cadivast 10/80 [AF] | [a] Caduet 10/80 [AS] |

# DERMATOLOGICALS

## ANTIFUNGALS FOR DERMATOLOGICAL USE

### ANTIFUNGALS FOR TOPICAL USE

#### *Imidazole and triazole derivatives*

## MICONAZOLE

**Authority Required (STREAMLINED)**

***6434***

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**miconazole nitrate 2% cream, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9027D NP | ‡1 | 2 | 0.00 | 19.76 | 21.30 | Daktarin [JT] |

**miconazole nitrate 2% powder, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9029F NP | ‡1 | 2 | 0.00 | 20.25 | 21.79 | Daktarin [JT] |

**miconazole nitrate 2% cream, 70 g**

| 9028E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 20.94 | 22.48 | Daktarin [JT] |

### *Other antifungals for topical use*

## TERBINAFINE

**Authority Required (STREAMLINED)**

***6434***

Fungal or yeast infection

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority Required (STREAMLINED)**

***6412***

Fungal or yeast infection

**Clinical criteria:**

- The condition must be fungal; **OR**
- The condition must be due to yeast.

**Population criteria:**

- Patient must be 18 years of age or less.

**terbinafine hydrochloride 1% cream, 15 g**

| 9160D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *40.46 | 25.00 | Lamisil [NP] |

# ANTIFUNGALS FOR SYSTEMIC USE

### *Antifungals for systemic use*

## GRISEOFULVIN

**griseofulvin 125 mg tablet, 100**

| 1460W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 24.72 | 25.00 | Grisovin [AS] |

**griseofulvin 500 mg tablet, 28**

| 2982Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 25.33 | 25.00 | Grisovin 500 [AS] |

## TERBINAFINE

**Authority Required**

***6395***

Onychomycosis

**Clinical criteria:**

- The condition must be proximal or extensive (greater than 80% nail involvement), **AND**
- Patient must have failed to respond to topical treatment, **AND**
- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; **OR**
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

The date of the pathology report must be provided at the time of application and must not be more than 12 months old

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**terbinafine 250 mg tablet, 42**

| 2804N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 25.16 | 25.00 | [a] APO-Terbinafine [TX] | [a] Tamsil [RW] |
| | | | | | | [a] Terbinafine-DRLA [RZ] | [a] Terbinafine Sandoz [SZ] |
| | | | | | | [a] TERBINAFINE-WGR [WG] | [a] Tinasil [AF] |

## TERBINAFINE

**Authority Required**

***6404***

Dermatophyte infection

**Clinical criteria:**

- Patient must have failed to respond to topical treatment.

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority Required**

***6453***

Dermatophyte infection

**Clinical criteria:**

- Patient must have failed to respond to topical treatment, **AND**
- Patient must have failed to respond to griseofulvin.

**Population criteria:**

- Patient must be 18 years of age or less.

**terbinafine 250 mg tablet, 42**

| 2285G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 25.16 | 25.00 | [a] APO-Terbinafine [TX] | [a] Tamsil [RW] |
| | | | | | | [a] Terbinafine-DRLA [RZ] | [a] Terbinafine Sandoz [SZ] |
| | | | | | | [a] TERBINAFINE-WGR [WG] | [a] Tinasil [AF] |

# ANTIPSORIATICS

## ANTIPSORIATICS FOR TOPICAL USE

### *Other antipsoriatics for topical use*

### CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

**Restricted benefit**

***6809***

Chronic stable plaque type psoriasis vulgaris

**Clinical criteria:**

- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g**

| 9494Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 39.21 | 25.00 | [a] Calcipotriol/Betamethasone Sandoz 50/500 [SZ] | [a] Daivobet [LO] |

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g**

| 11091R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 84.44 | 25.00 | [a] Klarvanta [XT] | |
| | | | [B]9.65 | 94.09 | 25.00 | [a] Enstilar [LO] | |

**Calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% cream, 60 g**

| 15203E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 64.07 | 25.00 | Wynzora 50/500 [KT] |

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 60 g**

| 15352B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 64.07 | 25.00 | Actobet 50/500 [KT] |

### CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

**Restricted benefit**

***14236***

Chronic stable plaque type psoriasis vulgaris

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g**

| 13577N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 1 | 0.00 | *64.06 | 25.00 | [a] Calcipotriol/Betamethasone Sandoz 50/500 [SZ] | [a] Daivobet [LO] |

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g**

| 13520N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 1 | 0.00 | *156.52 | 25.00 | [a] Klarvanta [XT] | |
| | | | [B]20.28 | *176.80 | 25.00 | [a] Enstilar [LO] | |

**Calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% cream, 60 g**

| 15212P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *113.78 | 25.00 | Wynzora 50/500 [KT] |

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 60 g**

| 15345P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *113.78 | 25.00 | Actobet 50/500 [KT] |

## ANTIPSORIATICS FOR SYSTEMIC USE

### *Retinoids for treatment of psoriasis*

### ACITRETIN

**Caution** This drug is a potent teratogen - pregnancy should be avoided during therapy and for at least three years after cessation of therapy.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority Required (STREAMLINED)**

***17316***

Severe intractable psoriasis

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where this prescription is to continue existing therapy with this medicine.

**Authority Required (STREAMLINED)**

***17272***

Severe disorders of keratinisation

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where this prescription is to continue existing therapy with this medicine.

**acitretin 10 mg capsule, 100**

| 2019G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 107.73 | 25.00 | [a] Neotigason [TB] | [a] ZETIN [RW] |

**acitretin 25 mg capsule, 100**

| 2020H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 208.73 | 25.00 | [a] Neotigason [TB] | [a] ZETIN [RW] |

## CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

### CORTICOSTEROIDS, PLAIN

### *Corticosteroids, weak (group I)*

### HYDROCORTISONE ACETATE

**Restricted benefit**

***4899***

Corticosteroid-responsive dermatoses

**hydrocortisone acetate 1% cream, 50 g**

| 2881P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 17.10 | 18.64 | [a] Cortic-DS 1% [LN] | |
| | | | [B]2.19 | 19.29 | 18.64 | [a] Sigmacort [AS] | |

**hydrocortisone acetate 1% ointment, 50 g**

| 2882Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 17.10 | 18.64 | [a] Cortic-DS 1% [LN] | |
| | | | [B]2.19 | 19.29 | 18.64 | [a] Sigmacort [AS] | |

### HYDROCORTISONE ACETATE

**Restricted benefit**

***4934***

Corticosteroid-responsive dermatoses

**hydrocortisone acetate 1% cream, 50 g**

| 5113D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 17.10 | 18.64 | [a] Cortic-DS 1% [LN] | |
| | | | [B]2.19 | 19.29 | 18.64 | [a] Sigmacort [AS] | |

**hydrocortisone acetate 1% ointment, 50 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5114E DP | ‡1 | 0 | 0.00 | 17.10 | 18.64 | [a] Cortic-DS 1% [LN] | |
| | | | [B]2.19 | 19.29 | 18.64 | [a] Sigmacort [AS] | |

## *Corticosteroids, moderately potent (group II)*

### TRIAMCINOLONE

**Restricted benefit**

***4924***

Corticosteroid-responsive dermatoses

**triamcinolone acetonide 0.02% cream, 100 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2117K NP | 2 | 0 | 0.00 | *21.84 | 23.38 | [a] Tricortone [LN] | |
| | | | [B]3.04 | *24.88 | 23.38 | [a] Aristocort 0.02% [AS] | |

**triamcinolone acetonide 0.02% ointment, 100 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2118L NP | 2 | 0 | 0.00 | *21.84 | 23.38 | [a] Tricortone [LN] | |
| | | | [B]3.04 | *24.88 | 23.38 | [a] Aristocort 0.02% [AS] | |

## *Corticosteroids, potent (group III)*

### BETAMETHASONE DIPROPIONATE

**Restricted benefit**

***4957***

Corticosteroid-responsive dermatoses

**betamethasone (as dipropionate) 0.05% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1115Q NP | 1 | 1 | 0.00 | 18.25 | 19.79 | [a] DIPROVANT [NB] | [a] Eleuphrat [AL] |
| | | | [B]2.28 | 20.53 | 19.79 | [a] Diprosone [AF] | |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1119X NP | 1 | 1 | 0.00 | 18.25 | 19.79 | [a] DIPROVANT [NB] | [a] Eleuphrat [AL] |
| | | | [B]2.28 | 20.53 | 19.79 | [a] Diprosone [AF] | |

### BETAMETHASONE DIPROPIONATE

**Authority Required (STREAMLINED)**

***6232***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10795E NP | 2 | 5 | 0.00 | *22.14 | 23.68 | [a] DIPROVANT [NB] | [a] Eleuphrat [AL] |
| | | | [B]4.56 | *26.70 | 23.68 | [a] Diprosone [AF] | |

**betamethasone (as dipropionate) 0.05% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10824Q NP | 2 | 5 | 0.00 | *22.14 | 23.68 | [a] DIPROVANT [NB] | [a] Eleuphrat [AL] |
| | | | [B]4.56 | *26.70 | 23.68 | [a] Diprosone [AF] | |

### BETAMETHASONE DIPROPIONATE

**Authority Required (STREAMLINED)**

***6246***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10800K NP | 4 | 5 | 0.00 | *29.92 | 25.00 | [a] DIPROVANT [NB] | [a] Eleuphrat [AL] |
| | | | [B]9.12 | *39.04 | 25.00 | [a] Diprosone [AF] | |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

| 10820L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *29.92 | 25.00 | [a] DIPROVANT [NB] | [a] Eleuphrat [AL] |
| | | | [B]9.12 | *39.04 | 25.00 | [a] Diprosone [AF] | |

## BETAMETHASONE DIPROPIONATE

**Authority Required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

| 10801L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *45.48 | 25.00 | [a] DIPROVANT [NB] | [a] Eleuphrat [AL] |
| | | | [B]18.24 | *63.72 | 25.00 | [a] Diprosone [AF] | |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

| 10816G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *45.48 | 25.00 | [a] DIPROVANT [NB] | [a] Eleuphrat [AL] |
| | | | [B]18.24 | *63.72 | 25.00 | [a] Diprosone [AF] | |

## BETAMETHASONE DIPROPIONATE

**Authority Required (STREAMLINED)**

***6231***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

| 10802M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 10 | 5 | 0.00 | *53.24 | 25.00 | [a] DIPROVANT [NB] | [a] Eleuphrat [AL] |
| | | | [B]22.80 | *76.04 | 25.00 | [a] Diprosone [AF] | |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

| 10823P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 10 | 5 | 0.00 | *53.24 | 25.00 | [a] DIPROVANT [NB] | [a] Eleuphrat [AL] |
| | | | [B]22.80 | *76.04 | 25.00 | [a] Diprosone [AF] | |

## BETAMETHASONE DIPROPIONATE

**Authority Required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

| 10813D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | 0.00 | *37.68 | 25.00 | [a] DIPROVANT [NB] | [a] Eleuphrat [AL] |
| | | | [B]13.68 | *51.36 | 25.00 | [a] Diprosone [AF] | |

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

| 10821M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | 0.00 | *37.68 | 25.00 | [a] DIPROVANT [NB] | [a] Eleuphrat [AL] |
| | | | [B]13.68 | *51.36 | 25.00 | [a] Diprosone [AF] | |

## BETAMETHASONE VALERATE

**Restricted benefit**

***4924***

Corticosteroid-responsive dermatoses

**betamethasone (as valerate) 0.02% cream, 100 g**

| 2812B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 0.00 | *24.70 | 25.00 | [a] Antroquoril [AL] | [b] Cortival 1/5 [LN] |
| | | | [B]3.92 | *28.62 | 25.00 | [b] Betnovate 1/5 [AS] | |
| | | | [B]4.78 | *29.48 | 25.00 | [a] Celestone-M [AF] | |

## BETAMETHASONE VALERATE

**Restricted benefit**

***4957***

Corticosteroid-responsive dermatoses

**betamethasone (as valerate) 0.05% cream, 15 g**

| 2813C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 17.10 | 18.64 | [a] Cortival 1/2 [LN] | |
| | | | [B]2.38 | 19.48 | 18.64 | [a] Betnovate 1/2 [AS] | |

## BETAMETHASONE VALERATE

**Authority Required (STREAMLINED)**

***6246***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

| 10794D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *25.32 | 25.00 | [a] Cortival 1/2 [LN] | |
| | | | [B]9.52 | *34.84 | 25.00 | [a] Betnovate 1/2 [AS] | |

## BETAMETHASONE VALERATE

**Authority Required (STREAMLINED)**

***6232***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

| 10799J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Cortival 1/2 [LN] | |
| | | | [B]4.76 | *24.60 | 21.38 | [a] Betnovate 1/2 [AS] | |

## BETAMETHASONE VALERATE

**Authority Required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

| 10807T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *36.28 | 25.00 | [a] Cortival 1/2 [LN] | |
| | | | [B]19.04 | *55.32 | 25.00 | [a] Betnovate 1/2 [AS] | |

## BETAMETHASONE VALERATE

**Authority Required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

| 10808W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | 0.00 | *30.78 | 25.00 | [a] Cortival 1/2 [LN] | |
| | | | [B]14.28 | *45.06 | 25.00 | [a] Betnovate 1/2 [AS] | |

## BETAMETHASONE VALERATE

**Authority Required (STREAMLINED)**

***6231***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**betamethasone (as valerate) 0.05% cream, 15 g**

| 10810Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 10 | 5 | 0.00 | *41.74 | 25.00 | [a] Cortival 1/2 [LN] | |
| | | | [B]23.80 | *65.54 | 25.00 | [a] Betnovate 1/2 [AS] | |

## METHYLPREDNISOLONE

**Restricted benefit**

***4957***

Corticosteroid-responsive dermatoses

**methylprednisolone aceponate 0.1% cream, 15 g**

| 8054X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 19.55 | 21.09 | [a] Supriad Cream [XT] | |
| | | | [B]3.79 | 23.34 | 21.09 | [a] Advantan [LO] | |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 8055Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 19.55 | 21.09 | [a] Metvant [NB] | [a] Supriad Ointment [XT] |
| | | | [B]3.79 | 23.34 | 21.09 | [a] Advantan [LO] | |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 8128T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 19.55 | 21.09 | [a] Metvant (Fatty) [NB] | [a] Supriad Fatty Ointment [XT] |
| | | | | | | [a] Tanilone (Fatty) [AS] | |
| | | | [B]3.79 | 23.34 | 21.09 | [a] Advantan (Fatty) [LO] | |

## METHYLPREDNISOLONE

**Restricted benefit**

***6302***

Eczema

**methylprednisolone aceponate 0.1% lotion, 20 g**

| 8618N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 20.15 | 21.69 | Advantan [LO] |

## METHYLPREDNISOLONE

**Authority Required (STREAMLINED)**

***6231***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

**methylprednisolone aceponate 0.1% cream, 15 g**

| 10833E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 10 | 5 | 0.00 | *66.24 | 25.00 | [a] Supriad Cream [XT] | |
| | | | [B]37.90 | *104.14 | 25.00 | [a] Advantan [LO] | |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 10843Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 10 | 5 | 0.00 | *66.24 | 25.00 | [a] Metvant (Fatty) [NB] | [a] Supriad Fatty Ointment [XT] |
| | | | | | | [a] Tanilone (Fatty) [AS] | |
| | | | [B]37.90 | 104.14 | 25.00 | [a] Advantan (Fatty) [LO] | |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 10845T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 10 | 5 | 0.00 | *66.24 | 25.00 | [a] Metvant [NB] | [a] Supriad Ointment [XT] |
| | | | [B]37.90 | *104.14 | 25.00 | [a] Advantan [LO] | |

**methylprednisolone aceponate 0.1% lotion, 20 g**

| 10830B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 5 | 0.00 | *43.29 | 25.00 | Advantan [LO] |

## METHYLPREDNISOLONE

**Authority Required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 10834F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *55.88 | 25.00 | [a] Metvant [NB] | [a] Supriad Ointment [XT] |
| | | | [B]30.32 | *86.20 | 25.00 | [a] Advantan [LO] | |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 10839L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *55.88 | 25.00 | [a] Metvant (Fatty) [NB] | [a] Supriad Fatty Ointment [XT] |
| | | | | | | [a] Tanilone (Fatty) [AS] | |
| | | | [B]30.32 | 86.20 | 25.00 | [a] Advantan (Fatty) [LO] | |

**methylprednisolone aceponate 0.1% cream, 15 g**

| 10851D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *55.88 | 25.00 | [a] Supriad Cream [XT] | |
| | | | [B]30.32 | *86.20 | 25.00 | [a] Advantan [LO] | |

## METHYLPREDNISOLONE

**Authority Required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**methylprednisolone aceponate 0.1% cream, 15 g**

| 10835G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | 0.00 | *45.48 | 25.00 | [a] Supriad Cream [XT] | |
| | | | [B]22.74 | *68.22 | 25.00 | [a] Advantan [LO] | |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 10844R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | 0.00 | *45.48 | 25.00 | [a] Metvant (Fatty) [NB] | [a] Supriad Fatty Ointment [XT] |
| | | | | | | [a] Tanilone (Fatty) [AS] | |
| | | | [B]22.74 | 68.22 | 25.00 | [a] Advantan (Fatty) [LO] | |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 10853F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | 0.00 | *45.48 | 25.00 | [a] Metvant [NB] | [a] Supriad Ointment [XT] |
| | | | [B]22.74 | *68.22 | 25.00 | [a] Advantan [LO] | |

## METHYLPREDNISOLONE

**Authority Required (STREAMLINED)**

***6246***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 10836H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *35.12 | 25.00 | [a] Metvant [NB] | [a] Supriad Ointment [XT] |
| | | | [B]15.16 | *50.28 | 25.00 | [a] Advantan [LO] | |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 10840M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *35.12 | 25.00 | [a] Metvant (Fatty) [NB] | [a] Supriad Fatty Ointment [XT] |
| | | | | | | [a] Tanilone (Fatty) [AS] | |
| | | | [B]15.16 | 50.28 | 25.00 | [a] Advantan (Fatty) [LO] | |

**methylprednisolone aceponate 0.1% cream, 15 g**

| 10855H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *35.12 | 25.00 | [a] Supriad Cream [XT] | |
| | | | [B]15.16 | *50.28 | 25.00 | [a] Advantan [LO] | |

**methylprednisolone aceponate 0.1% lotion, 20 g**

| 10838K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *31.74 | 25.00 | Advantan [LO] |

## METHYLPREDNISOLONE

**Authority Required (STREAMLINED)**

***6232***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**methylprednisolone aceponate 0.1% cream, 15 g**

| 10842P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.74 | 25.00 | [a] Supriad Cream [XT] | |
| | | | [B]7.58 | *32.32 | 25.00 | [a] Advantan [LO] | |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 10846W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.74 | 25.00 | [a] Metvant [NB] | [a] Supriad Ointment [XT] |
| | | | [B]7.58 | *32.32 | 25.00 | [a] Advantan [LO] | |

**methylprednisolone aceponate 0.1% ointment, 15 g**

| 10848Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.74 | 25.00 | [a] Metvant (Fatty) [NB] | [a] Supriad Fatty Ointment [XT] |
| | | | | | | [a] Tanilone (Fatty) [AS] | |
| | | | [B]7.58 | 32.32 | 25.00 | [a] Advantan (Fatty) [LO] | |

**methylprednisolone aceponate 0.1% lotion, 20 g**

| 10856J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *25.94 | 25.00 | Advantan [LO] |

## METHYLPREDNISOLONE

**Authority Required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**Authority Required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**methylprednisolone aceponate 0.1% lotion, 20 g**

| 10852E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *37.52 | 25.00 | Advantan [LO] |

## MOMETASONE

**Restricted benefit**

***4957***

Corticosteroid-responsive dermatoses

**mometasone furoate 0.1% lotion, 30 mL**

| 8043H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 19.46 | 21.00 | [a] Novasone [AF] | [a] Zatamil [EO] |
| | | | [B]5.31 | 24.77 | 21.00 | [a] Elocon [AL] | |

**mometasone furoate 0.1% cream, 15 g**

| 1913Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 18.10 | 19.64 | [a] GLENMARK MOMETASONE Alcohol Free [JM] | [a] Novasone [AF] |
| | | | [B]3.33 | 21.43 | 19.64 | [a] Elocon Alcohol Free [AL] | |

**mometasone furoate 0.1% ointment, 15 g**

| 1915T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 18.10 | 19.64 | [a] GLENMARK MOMETASONE [JM] | [a] Novasone [AF] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1915T | | | | | | [a] Zatamil [EO] | |
| | | | [B]3.33 | 21.43 | 19.64 | [a] Elocon [AL] | |

## MOMETASONE

**Authority Required (STREAMLINED)**

***6231***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover >80% of the patient's body surface area.

### mometasone furoate 0.1% lotion, 30 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10804P | | | | | | | |
| NP | 5 | 5 | 0.00 | *39.84 | 25.00 | [a] Novasone [AF] | [a] Zatamil [EO] |
| | | | [B]26.55 | *66.39 | 25.00 | [a] Elocon [AL] | |

### mometasone furoate 0.1% ointment, 15 g

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10791Y | | | | | | | |
| NP | 10 | 5 | 0.00 | *51.74 | 25.00 | [a] GLENMARK MOMETASONE [JM] | [a] Novasone [AF] |
| | | | | | | [a] Zatamil [EO] | |
| | | | [B]33.30 | 85.04 | 25.00 | [a] Elocon [AL] | |

### mometasone furoate 0.1% cream, 15 g

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10792B | | | | | | | |
| NP | 10 | 5 | 0.00 | *51.74 | 25.00 | [a] GLENMARK MOMETASONE Alcohol Free [JM] | [a] Novasone [AF] |
| | | | [B]33.30 | *85.04 | 25.00 | [a] Elocon Alcohol Free [AL] | |

## MOMETASONE

**Authority Required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

### mometasone furoate 0.1% ointment, 15 g

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10793C | | | | | | | |
| NP | 8 | 5 | 0.00 | *44.28 | 25.00 | [a] GLENMARK MOMETASONE [JM] | [a] Novasone [AF] |
| | | | | | | [a] Zatamil [EO] | |
| | | | [B]26.64 | 70.92 | 25.00 | [a] Elocon [AL] | |

### mometasone furoate 0.1% cream, 15 g

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10818J | | | | | | | |
| NP | 8 | 5 | 0.00 | *44.28 | 25.00 | [a] GLENMARK MOMETASONE Alcohol Free [JM] | [a] Novasone [AF] |
| | | | [B]26.64 | *70.92 | 25.00 | [a] Elocon Alcohol Free [AL] | |

## MOMETASONE

**Authority Required (STREAMLINED)**

***6246***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 20-40% of the patient's body surface area.

### mometasone furoate 0.1% lotion, 30 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10826T | | | | | | | |
| NP | 3 | 5 | 0.00 | *29.67 | 25.00 | [a] Novasone [AF] | [a] Zatamil [EO] |
| | | | [B]15.93 | *45.60 | 25.00 | [a] Elocon [AL] | |

### mometasone furoate 0.1% cream, 15 g

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10809X | | | | | | | |
| NP | 4 | 5 | 0.00 | *29.32 | 25.00 | [a] GLENMARK MOMETASONE Alcohol Free [JM] | [a] Novasone [AF] |
| | | | [B]13.32 | *42.64 | 25.00 | [a] Elocon Alcohol Free [AL] | |

**mometasone furoate 0.1% ointment, 15 g**

| 10814E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *29.32 | 25.00 | [a] GLENMARK MOMETASONE [JM] | [a] Novasone [AF] |
| | | | | | | [a] Zatamil [EO] | |
| | | | [B]13.32 | 42.64 | 25.00 | [a] Elocon [AL] | |

## MOMETASONE

**Authority Required (STREAMLINED)**

***6232***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 10-20% of the patient's body surface area.

**mometasone furoate 0.1% lotion, 30 mL**

| 10819K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.56 | 25.00 | [a] Novasone [AF] | [a] Zatamil [EO] |
| | | | [B]10.62 | *35.18 | 25.00 | [a] Elocon [AL] | |

**mometasone furoate 0.1% ointment, 15 g**

| 10812C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] GLENMARK MOMETASONE [JM] | [a] Novasone [AF] |
| | | | | | | [a] Zatamil [EO] | |
| | | | [B]6.66 | 28.50 | 23.38 | [a] Elocon [AL] | |

**mometasone furoate 0.1% cream, 15 g**

| 10827W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] GLENMARK MOMETASONE Alcohol Free [JM] | [a] Novasone [AF] |
| | | | [B]6.66 | *28.50 | 23.38 | [a] Elocon Alcohol Free [AL] | |

## MOMETASONE

**Authority Required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**mometasone furoate 0.1% cream, 15 g**

| 10815F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | 0.00 | *36.78 | 25.00 | [a] GLENMARK MOMETASONE Alcohol Free [JM] | [a] Novasone [AF] |
| | | | [B]19.98 | *56.76 | 25.00 | [a] Elocon Alcohol Free [AL] | |

**mometasone furoate 0.1% ointment, 15 g**

| 10828X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | 0.00 | *36.78 | 25.00 | [a] GLENMARK MOMETASONE [JM] | [a] Novasone [AF] |
| | | | | | | [a] Zatamil [EO] | |
| | | | [B]19.98 | 56.76 | 25.00 | [a] Elocon [AL] | |

## MOMETASONE

**Authority Required (STREAMLINED)**

***6218***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient's body surface area.

**Authority Required (STREAMLINED)**

***6263***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient's body surface area.

**mometasone furoate 0.1% lotion, 30 mL**

| 10805Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *34.76 | 25.00 | [a] Novasone [AF] | [a] Zatamil [EO] |
| | | | [B]21.24 | *56.00 | 25.00 | [a] Elocon [AL] | |

### *Corticosteroids, very potent (group IV)*

## CLOBETASOL

**Authority Required (STREAMLINED)**

***17270***

Moderate to severe scalp psoriasis

**Clinical criteria:**

- The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; **OR**
- The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.

**Population criteria:**

- Patient must be at least 18 years of age.

**clobetasol propionate 0.05% shampoo, 125 mL**

| 10080M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 47.38 | 25.00 | Clobex [GA] |

## CLOBETASOL

**Note** Treatment should be limited to a maximum of 15 g per week.
**Note** This preparation is only suitable for small areas of affected skin.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***16464***

Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must be resistant to lower potency topical corticosteroid therapy.

**clobetasol propionate 0.05% ointment, 30 g**

| 14808J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 21.97 | 23.51 | Xobet [XT] |

**clobetasol propionate 0.05% cream, 30 g**

| 14832P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 21.97 | 23.51 | Xobet [XT] |

# ANTI-ACNE PREPARATIONS

## ANTI-ACNE PREPARATIONS FOR TOPICAL USE

### *Retinoids for topical use in acne*

## ADAPALENE + BENZOYL PEROXIDE

**Restricted benefit**

***4961***

Severe acne vulgaris

Treatment Phase: Acute treatment

**Clinical criteria:**

- The treatment must in combination with an oral antibiotic.

**adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g**

| 8954G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 30.62 | 25.00 | Epiduo [GA] |

## ADAPALENE + BENZOYL PEROXIDE

**Restricted benefit**

***4898***

Severe acne vulgaris

**Clinical criteria:**

- The treatment must be maintenance therapy.

**adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g**

| 8955H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 3 | 0.00 | 30.62 | 25.00 | Epiduo [GA] |

## ADAPALENE + BENZOYL PEROXIDE

**Restricted benefit**

***14275***

Severe acne vulgaris

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be maintenance therapy.

**adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g**

| 13363H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 3 | 0.00 | *46.88 | 25.00 | Epiduo [GA] |

# ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE

## *Retinoids for treatment of acne*

## ISOTRETINOIN

**Caution** This drug causes birth defects.

**Caution** This drug has been reported to cause other frequent and potentially serious toxicity.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority Required (STREAMLINED)**

***17268***

Severe cystic acne

**Clinical criteria:**

- The condition must be unresponsive to other therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where this prescription is to continue existing therapy with this medicine.

**isotretinoin 5 mg capsule, 60**

| 11716P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 25.84 | 25.00 | Oratane [RF] |

**isotretinoin 10 mg capsule, 60**

| 2591J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 30.93 | 25.00 | [a] APO-Isotretinoin [TX] | [a] Dermatane [ZS] |
| | | | | | | [a] Isotretinoin GX [SZ] | [a] Isotretinoin Lupin [GQ] |
| | | | | | | [a] ISOTRETINOIN-WGR [WG] | [a] Oratane [RF] |

**isotretinoin 30 mg capsule, 60**

| 11921K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 62.83 | 25.00 | Oratane [RF] |

**isotretinoin 40 mg capsule, 30**

| 2549E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 46.67 | 25.00 | [a] Dermatane [ZS] | [a] Oratane [RF] |

## ISOTRETINOIN

**Caution** This drug causes birth defects.

**Caution** This drug has been reported to cause other frequent and potentially serious toxicity.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Pharmaceutical benefits that have form pack size isotretinoin 20 mg capsule, 60 and isotretinoin 20 mg capsule, 30 are equivalent for the purposes of substitution.

**Authority Required (STREAMLINED)**

***17268***

Severe cystic acne

**Clinical criteria:**

- The condition must be unresponsive to other therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where this prescription is to continue existing therapy with this medicine.

**isotretinoin 20 mg capsule, 60**

| 2592K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 40.21 | 25.00 | [a] APO-Isotretinoin [TX] | [a] Dermatane [ZS] |
| | | | | | | [a] Isotretinoin Dr.Reddy's [RZ] | [a] Isotretinoin GX [SZ] |
| | | | | | | [a] Isotretinoin Lupin [GQ] | [a] ISOTRETINOIN-WGR [WG] |
| | | | | | | [a] Oratane [RF] | [a] Pharmacor Isotretinoin [CR] |

**isotretinoin 20 mg capsule, 30**

| 11621P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *40.20 | 25.00 | [a] Isotretinoin Dr.Reddy's [RZ] | [a] Roaccutane [PB] |

# OTHER DERMATOLOGICAL PREPARATIONS

## OTHER DERMATOLOGICAL PREPARATIONS

### *Antihidrotics*

### GLYCOPYRRONIUM

**Caution** The anticholinergic effect of this medicine may exacerbate pre-existing medical conditions including but not limited to cardiac arrhythmias.

**Authority Required (STREAMLINED)**

***18870***

Severe primary axillary hyperhidrosis

**Clinical criteria:**

- Patient must have previously failed topical aluminium chloride after one to two months of treatment; **OR**
- Patient must be intolerant to topical aluminium chloride treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Glycopyrronium 2.2 mg/actuation cream, 124 actuations**

| 15337F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 2 | 0.00 | 156.24 | 25.00 | Axhidrox [KT] |

### *Agents for dermatitis, excluding corticosteroids*

### DUPILUMAB

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL syringes; and
- dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL pen devices.

**Note** Instructions on the use of the Eczema Area and Severity Index and copyright details can be found here:
https://www.dupixent.co.uk/-/media/EMS/Conditions/Dermatology/Brands/Dupixent-UK/global/1051-EASI-Leaflet-v6-webready.pdf

**Note** Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here:
https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17047***

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment of the whole body

**Clinical criteria:**

- Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this PBS indication.

**Treatment criteria:**

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist.

**Population criteria:**

- Patient must be at least 12 years of age.

State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.

**Note** Instructions on the use of the Physician's Global Assessment (5-point scale) can be obtained from Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

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**Authority Required**

***11374***

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment of the whole body

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the whole body, **AND**
- Patient must have achieved an adequate response within the first 16 weeks of treatment; **OR**
- Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; **OR**
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication.

**Treatment criteria:**

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist.

For the purposes of this restriction, an adequate response to treatment is defined as:

(a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and

(b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

State each of the current EASI and DLQI scores for this authority application.

**Authority Required**

***17076***

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment of the face and/or hands

**Clinical criteria:**

- The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; **OR**
- The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this PBS indication.

**Treatment criteria:**

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist.

**Population criteria:**

- Patient must be at least 12 years of age.

State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for:

(i) erythema,

(ii) oedema/papulation,

(iii) excoriation,

(iv) lichenification

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores.

The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.

**Authority Required**

***11377***

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment of the face and/or hands

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the face/hands, **AND**
- Patient must have achieved an adequate response within the first 16 weeks of treatment; **OR**
- Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; **OR**
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication.

**Treatment criteria:**

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist.

For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as:

(a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or

(ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and

(b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes

### dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

12291X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,757.67 | 25.00 | [a] Dupixent [SW] |

### dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices

15035H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,757.67 | 25.00 | [a] Dupixent [SW] |

## DUPILUMAB

**Note** Pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL syringes and pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL pen devices are equivalent for the purposes of substitution.

**Note** Instructions on the use of the Eczema Area and Severity Index and copyright details can be found here:
https://www.dupixent.co.uk/-/media/EMS/Conditions/Dermatology/Brands/Dupixent-UK/global/1051-EASI-Leaflet-v6-webready.pdf

**Note** Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here:
https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17047***

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment of the whole body

**Clinical criteria:**

- Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this PBS indication.

**Treatment criteria:**

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist.

**Population criteria:**

- Patient must be at least 12 years of age.

State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.

**Note** Instructions on the use of the Physician's Global Assessment (5-point scale) can be obtained from Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

**Authority Required**

***11374***

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment of the whole body

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the whole body, **AND**
- Patient must have achieved an adequate response within the first 16 weeks of treatment; **OR**
- Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; **OR**
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication.

**Treatment criteria:**

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist.

For the purposes of this restriction, an adequate response to treatment is defined as:

(a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and

(b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

State each of the current EASI and DLQI scores for this authority application.

**Authority Required**

***17076***

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment of the face and/or hands

**Clinical criteria:**

- The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; **OR**
- The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this PBS indication.

**Treatment criteria:**

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist.

**Population criteria:**

- Patient must be at least 12 years of age.

State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for:

(i) erythema,

(ii) oedema/papulation,

(iii) excoriation,

(iv) lichenification

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores.

The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.

**Authority Required**

***11377***

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment of the face and/or hands

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the face/hands, **AND**
- Patient must have achieved an adequate response within the first 16 weeks of treatment; **OR**
- Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; **OR**
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication.

**Treatment criteria:**

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist.

For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as:

(a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or

(ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and

(b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes

**dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes**

12292Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,757.67 | 25.00 | [a] Dupixent [SW] |

**dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices**

| 14979J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,757.67 | 25.00 | [a] Dupixent [SW] |

## PIMECROLIMUS

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***5482***

Atopic dermatitis

**Population criteria:**

- Patient must be at least 3 months of age.

**Clinical criteria:**

- The condition must be on the patient's face; **OR**
- The condition must be on the patient's eyelid, **AND**
- Patient must have 1 or more of the following contraindications to topical corticosteroids: (i) perioral dermatitis; (ii) periorbital dermatitis; (iii) rosacea; (iv) epidermal atrophy; (v) dermal atrophy; (vi) allergy to topical corticosteroids; (vii) cataracts; (viii) glaucoma; (ix) raised intraocular pressure, **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

**Authority Required (STREAMLINED)**

***5472***

Atopic dermatitis

Treatment Phase: Short-term (up to 3 weeks) intermittent treatment

**Population criteria:**

- Patient must be at least 3 months of age.

**Clinical criteria:**

- The condition must be on the patient's face; **OR**
- The condition must be on the patient's eyelid, **AND**
- Patient must have failed to achieve satisfactory disease control with intermittent topical corticosteroid therapy, **AND**
- The condition must have been initially diagnosed more than three months prior to this treatment, **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:

(i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or

(ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or

(iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or

(iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions

**pimecrolimus 1% cream, 15 g**

| 8802G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 34.31 | 25.00 | Elidel [GO] |

## TACROLIMUS

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***19259***

Moderate to severe atopic dermatitis

Treatment Phase: Flare treatment

**Clinical criteria:**

- Patient must have 1 or more of the following contraindications to topical corticosteroids: (i) perioral dermatitis; (ii) periorbital dermatitis; (iii) rosacea; (iv) epidermal atrophy; (v) dermal atrophy; (vi) allergy to topical corticosteroids; (vii) cataracts; (viii) glaucoma; (ix) raised intraocular pressure; **OR**
- The condition must not have been adequately controlled with topical corticosteroid therapy.

Inadequate control of this condition with topical corticosteroid therapy is defined as:

(i) no clearance of the skin despite at least 2 weeks of a potent topical corticosteroid for the body or a mild topical corticosteroid for the face and eyelids, applied every day; or

(ii) clearing of the skin with at least 2 weeks of a potent topical corticosteroid for the body or a mild topical corticosteroid for the face and eyelids, applied every day, but almost immediate and significant flare in disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions.

Treatment should be discontinued, and further treatment options should be considered if no signs of improvement are seen after 2 weeks of treatment.

Once clearance or near clearance of atopic dermatitis is achieved, patients should cease tacrolimus treatment and reinitiate only if there is a flare of their atopic dermatitis that meets the PBS eligibility criteria.

**Tacrolimus 0.1% ointment, 30 g**

| 15542B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 54.27 | 25.00 | aZematop [XT] |

## *Other dermatologicals*

## DAPSONE

**Dapsone 50 mg tablet, 100**

| 15168H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 319.77 | 25.00 | DAPSOMED [DZ] |

**dapsone 100 mg tablet, 100**

| 1272Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 390.28 | 25.00 | [a] DAPSOMED [DZ] | [a] Link Medical Products Pty Ltd [LM] |

## DAPSONE

**Note** Pharmaceutical benefits that have the brand Dapsone Tablets, USP 25 mg (Rising Pharmaceuticals, USA) may be substituted for pharmaceutical benefits that have the brand Link Medical Products Pty Ltd in case of shortage.

**dapsone 25 mg tablet, 100**

| 8801F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 319.77 | 25.00 | [a] Link Medical Products Pty Ltd [LM] |

**dapsone 25 mg tablet, 100**

| 15517Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 297.93 | 25.00 | [a] Dapsone Tablets, USP 25 mg (Rising Pharmaceuticals, USA) [LM] |

## IMIQUIMOD

**Note** The patient or carer must be able to understand and administer the imiquimod dosing regimen.

**Note** Treatment of recurrent (previously treated) lesions will not be authorised.

**Note** Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4229***

Superficial basal cell carcinoma

**Clinical criteria:**

- The condition must be previously untreated, **AND**
- The condition must be confirmed by biopsy, **AND**
- Patient must have normal immune function, **AND**
- The condition must not be suitable for treatment with surgical excision; **OR**
- The condition must not be suitable for treatment with cryotherapy; **OR**
- The condition must not be suitable for treatment with curettage with diathermy, **AND**
- Patient must require topical drug therapy.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

**imiquimod 5% cream, 12 x 250 mg sachets**

| 2546B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 87.63 | 25.00 | [a] APO-Imiquimod [TX] | |
| | | | [B]3.20 | 90.83 | 25.00 | [a] Aldara [IL] | |

**imiquimod 5% cream, 2 x 2 g**

| 2637T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 8.09 | 95.72 | 25.00 | [a] Aldara Pump [IL] |

# GENITO URINARY SYSTEM AND SEX HORMONES

## OTHER GYNECOLOGICALS

### CONTRACEPTIVES FOR TOPICAL USE

#### *Intrauterine contraceptives*

### LEVONORGESTREL

**Restricted benefit**
***5214***
Contraception

**levonorgestrel 19.5 mg intrauterine drug delivery system, 1 system**

| 11909T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 167.79 | 25.00 | Kyleena [SY] |

**levonorgestrel 52 mg intrauterine drug delivery system, 1 system**

| 14705Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 187.14 | 25.00 | Mirena [BN] |

### LEVONORGESTREL

**Restricted benefit**
***5135***
Idiopathic menorrhagia
**Clinical criteria:**

- The treatment must be in a patient where oral treatments are ineffective.

**Restricted benefit**
***5289***
Idiopathic menorrhagia
**Clinical criteria:**

- The treatment must be in a patient where oral treatments are contraindicated.

**levonorgestrel 52 mg intrauterine drug delivery system, 1 system**

| 8633J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 187.14 | 25.00 | Mirena [BN] |

#### *Intravaginal contraceptives*

### ETONOGESTREL + ETHINYLESTRADIOL

**etonogestrel 120 microgram/24 hours + ethinylestradiol 15 microgram/24 hours vaginal drug delivery system, 3 rings**

| 15074J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 3 | 0.00 | 61.76 | 25.00 | NuvaRing [OQ] |

## OTHER GYNECOLOGICALS

#### *Prolactine inhibitors*

### BROMOCRIPTINE

**Restricted benefit**
***5172***
Prevention of the onset of lactation
**Clinical criteria:**

- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

**bromocriptine 2.5 mg tablet, 30**

| 1444B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 23.71 | 25.00 | Parlodel [SZ] |

### BROMOCRIPTINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**
***6717***
Acromegaly

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***6718***
Parkinson disease

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***6787***
Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***6706***
Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***6707***
Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***6719***
Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**bromocriptine 2.5 mg tablet, 30**

1443Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *33.06 | 25.00 | Parlodel [SZ] |

## BROMOCRIPTINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***14914***
Acromegaly

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***15028***
Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***15043***
Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom surgery is not indicated.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***14981***
Pathological hyperprolactinaemia
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had surgery for this condition with incomplete resolution.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**
***15044***
Pathological hyperprolactinaemia
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom radiotherapy is not indicated.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**
***15017***
Pathological hyperprolactinaemia
**Clinical criteria:**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had radiotherapy for this condition with incomplete resolution.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

### bromocriptine 2.5 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13979R | 4 | 5 | 0.00 | *51.76 | 25.00 | Parlodel [SZ] |

## CABERGOLINE

**Restricted benefit**
***5172***
Prevention of the onset of lactation
**Clinical criteria:**
- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

### cabergoline 500 microgram tablet, 2

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8115D NP MW | 1 | 0 | 0.00 | 22.63 | 24.17 | Dostinex [PF] |

## CABERGOLINE

**Restricted benefit**
***5136***
Pathological hyperprolactinaemia
**Clinical criteria:**
- Patient must be one in whom surgery is not indicated.

**Restricted benefit**
***5137***
Pathological hyperprolactinaemia
**Clinical criteria:**
- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**
***5398***
Pathological hyperprolactinaemia
**Clinical criteria:**
- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**
***5357***
Pathological hyperprolactinaemia
**Clinical criteria:**
- Patient must have had radiotherapy for this condition with incomplete resolution.

**cabergoline 500 microgram tablet, 8**

| 8114C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 47.44 | 25.00 | [a] Dostamine [NB] | [a] Dostinex [PF] |

## CABERGOLINE

**Restricted benefit**

***14918***

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom surgery is not indicated.

**Restricted benefit**

***15005***

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**

***14959***

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**

***14983***

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had radiotherapy for this condition with incomplete resolution.

**cabergoline 500 microgram tablet, 8**

| 13901P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *80.52 | 25.00 | [a] Dostamine [NB] | [a] Dostinex [PF] |

# SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

## HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE

### *Progestogens and estrogens, fixed combinations*

## DROSPIRENONE + ETHINYLESTRADIOL

**drospirenone 3 mg + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 28**

| 14711G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 3 | 3 | 0.00 | *61.77 | 25.00 | [a] Brooklynn [HJ] | [a] Isabelle [GQ] |
| | | | | | | [a] Mila [NB] | [a] Rosalee [SZ] |
| | | | | | | [a] Yasmin [XW] | [a] Yelena [XT] |

**drospirenone 3 mg + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 3 x 28**

| 14725B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 3 | 0.00 | 61.76 | 25.00 | [a] Brooklynn [HJ] | [a] Isabelle [GQ] |
| | | | | | | [a] Mila [NB] | [a] Rosalee [SZ] |
| | | | | | | [a] Yasmin [XW] | [a] Yelena [XT] |

## DROSPIRENONE + ETHINYLESTRADIOL

**Note** Pharmaceutical benefits that have the form drospirenone 3 mg + ethinylestradiol 20 microgram tablet [24] (&) inert substance tablet [4], 3 x 28 are equivalent for the purposes of substitution.

**drospirenone 3 mg + ethinylestradiol 20 microgram tablet [24] (&) inert substance tablet [4], 3 x 28**

| 14709E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 3 | 0.00 | 61.76 | 25.00 | [a] Yaz [XW] |

**drospirenone 3 mg + ethinylestradiol 20 microgram tablet [24] (&) inert substance tablet [4], 3 x 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14941J | | | | | | | |
| NP MW | 1 | 3 | 0.00 | 61.76 | 25.00 | [a] Bella [GQ] | [a] Brooke [HJ] |
| | | | | | | [a] Rosie [SZ] | [a] YANA [XT] |

## DROSPIRENONE + ETHINYLESTRADIOL

**Note** Pharmaceutical benefits that have the form drospirenone 3 mg + ethinylestradiol 20 microgram tablet [24] (&) inert substance tablet [4], 28 are equivalent for the purposes of substitution.

**drospirenone 3 mg + ethinylestradiol 20 microgram tablet [24] (&) inert substance tablet [4], 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14710F | | | | | | |
| NP MW | 3 | 3 | 0.00 | *61.77 | 25.00 | [a] Yaz [XW] |

**drospirenone 3 mg + ethinylestradiol 20 microgram tablet [24] (&) inert substance tablet [4], 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14954C | | | | | | | |
| NP MW | 3 | 3 | 0.00 | *61.77 | 25.00 | [a] Bella [GQ] | [a] Brooke [HJ] |
| | | | | | | [a] Rosie [SZ] | [a] YANA [XT] |

## ESTETROL + DROSPIRENONE

**estetrol 14.2 mg + drospirenone 3 mg tablet [24] (&) inert substance tablet [4], 3 x 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15054H | | | | | | |
| NP MW | 1 | 3 | 0.00 | 61.76 | 25.00 | Nextstellis [YN] |

## LEVONORGESTREL + ETHINYLESTRADIOL

**levonorgestrel 100 microgram + ethinylestradiol 20 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2416E | | | | | | |
| NP MW | 1 | 2 | 0.00 | 20.28 | 21.82 | Femme-Tab ED 20/100 [AE] |

**levonorgestrel 125 microgram + ethinylestradiol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1456P | | | | | | |
| NP MW | 1 | 2 | 0.00 | 23.93 | 25.00 | Microgynon 50 ED [XW] |

**levonorgestrel 150 microgram + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1394J | | | | | | | |
| NP MW | 1 | 2 | 0.00 | 18.60 | 20.14 | [a] Eleanor 150/30 ED [XT] | [a] Evelyn 150/30 ED [GQ] |
| | | | | | | [a] Femme-Tab ED 30/150 [AE] | [a] Lenest 30 ED [AF] |
| | | | | | | [a] LEVETH 150/30 ED [WG] | [a] Micronelle 30 ED [TX] |
| | | | [B]5.53 | 24.13 | 20.14 | [a] Levlen ED [XW] | |

## NORETHISTERONE + ETHINYLESTRADIOL

**norethisterone 500 microgram + ethinylestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2774B | | | | | | |
| NP MW | 1 | 2 | 0.00 | 25.37 | 25.00 | Norimin 28 Day [FZ] |

## NORETHISTERONE + ETHINYLESTRADIOL

**Note** Pharmaceutical benefits that have the form norethisterone 1 mg + ethinylestradiol 35 microgram tablet in a 4 pack of 28 tablets can be substituted for a 3 pack of 28 tablets in the case of a shortage.

**norethisterone 1 mg + ethinylestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2775C | | | | | | |
| NP MW | 1 | 2 | 0.00 | 25.37 | 25.00 | Norimin-1 28 Day [FZ] |

### *Progestogens and estrogens, sequential preparations*

## LEVONORGESTREL + ETHINYLESTRADIOL

**levonorgestrel 50 microgram + ethinylestradiol 30 microgram tablet [6] (&) levonorgestrel 75 microgram + ethinylestradiol 40 microgram tablet [5] (&) levonorgestrel 125 microgram + ethinylestradiol 30 microgram tablet [10] (&) inert substance tablet [7], 4 x 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1392G | | | | | | | |
| NP MW | 1 | 2 | 0.00 0.00 | 21.85 | 23.39 | Trifeme 28 [FZ] | [a] Logynon ED [SY] |
| | | | [B]13.15 | 35.00 | 23.39 | [a] Triquilar ED [BN] | |

### *Progestogens*

## DROSPIRENONE

**Note** Pharmaceutical benefits that have the form drospirenone 4 mg tablet [24] (&) inert substance tablet [4], 4 x 28 and pharmaceutical benefits that have the form drospirenone 4 mg tablet [24] (&) inert substance tablet [4], 28 are equivalent for the purposes of substitution when the maximum quantity of 4 x 28 tablets is dispensed.

### drospirenone 4 mg tablet [24] (&) inert substance tablet [4], 4 x 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14791L NP MW | 1 | 2 | 0.00 | 77.57 | 25.00 | [a] Lucinda [GQ] | [a] Slinda [HB] |

### drospirenone 4 mg tablet [24] (&) inert substance tablet [4], 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14875X NP MW | ‡4 | 2 | 0.00 | *77.56 | 25.00 | [a] Lucinda [GQ] | [a] Slinda [HB] |

## ETONOGESTREL

### etonogestrel 68 mg implant, 1

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8487Q NP MW | 1 | 0 | 0.00 | 167.79 | 25.00 | Implanon NXT [OQ] |

## LEVONORGESTREL

### levonorgestrel 30 microgram tablet, 112 tablets [4 x 28]

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2913H NP MW | 1 | 2 | 0.00 | 21.83 | 23.37 | [a] Microlut 28 [XW] | [a] Mirolesa [LJ] |

## MEDROXYPROGESTERONE

### medroxyprogesterone acetate 150 mg/mL injection, 1 mL syringe

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14160G NP MW | 1 | 1 | 0.00 | 28.07 | 25.00 | Depo-Provera [PF] |

## NORETHISTERONE

### norethisterone 350 microgram tablet, 4 x 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1967M NP MW | 1 | 2 | 0.00 | 25.37 | 25.00 | Noriday 28 Day [PF] |

# ANDROGENS

## *3-oxoandrosten (4) derivatives*

## TESTOSTERONE

**Authority Required**

***6910***

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority Required**

***6324***

Androgen deficiency

**Clinical criteria:**

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority Required**

***6933***

Micropenis

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority Required**

***6919***

Pubertal induction

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority Required**

***6934***

Constitutional delay of growth or puberty

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

### testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations

| 10380H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 4 | 0.00 | 77.90 | 25.00 | Testogel [HB] |

### testosterone 2% (23 mg/actuation) gel, 56 actuations

| 11740X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 83.19 | 25.00 | Testavan [IX] |

### testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets

| 8830R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 77.90 | 25.00 | Testogel [HB] |

## TESTOSTERONE

**Authority Required**

***15015***

Androgen deficiency

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority Required**

***14912***

Androgen deficiency

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must not have an established pituitary or testicular disorder, **AND**

- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority Required**

***14913***

Micropenis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority Required**

***14955***

Pubertal induction

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority Required**

***14956***

Constitutional delay of growth or puberty

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

### testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations

| 13924W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 4 | 0.00 | *142.80 | 25.00 | Testogel [HB] |

### testosterone 2% (23 mg/actuation) gel, 56 actuations

| 14025E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *153.90 | 25.00 | Testavan [IX] |

### testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets

| 13983Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *142.80 | 25.00 | Testogel [HB] |

## TESTOSTERONE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***16166***

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

**Authority Required**

***16211***

Androgen deficiency

**Clinical criteria:**

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority Required**

***16204***

Micropenis

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

**Authority Required**

***16212***

Pubertal induction

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

**Authority Required**

***16194***

Constitutional delay of growth or puberty

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

### testosterone 5% (50 mg/mL) cream, 50 mL

10378F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 1 | 0.00 | 105.62 | 25.00 | AndroForte 5 [LX] |

NP

## TESTOSTERONE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***16186***

Androgen deficiency

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

**Authority Required**

***16214***

Androgen deficiency

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

**Authority Required**

***16206***

Micropenis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

**Authority Required**

***16207***

Pubertal induction

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

**Authority Required**

***16195***

Constitutional delay of growth or puberty

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

### testosterone 5% (50 mg/mL) cream, 50 mL

14563L

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡2 | 1 | 0.00 | *201.00 | 25.00 | AndroForte 5 [LX] |

## TESTOSTERONE UNDECANOATE

**Authority Required**

***6910***

Androgen deficiency

**Clinical criteria:**

- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority Required**

***6324***

Androgen deficiency

**Clinical criteria:**

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

- Patient must be aged 40 years or older.

**Treatment criteria:**

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR
(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).
Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.
The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.
The name of the specialist must be included in the authority application.

**Authority Required**

***6933***
Micropenis

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority Required**

***6919***
Pubertal induction

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

**Authority Required**

***6934***
Constitutional delay of growth or puberty

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

### testosterone undecanoate 1 g/4 mL modified release injection, 4 mL vial

| 10205D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 92.91 | 25.00 | [a] Gonadron [RA] | [a] Reandron 1000 [AS] |
| | | | | | | [a] REJUNON 1000 [JU] | [a] Testosterone ADVZ 1000 [BZ] |

## ESTROGENS

### *Natural and semisynthetic estrogens, plain*

### ESTRADIOL

#### estradiol 10 microgram modified release pessary, 18

| 10203B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 30.42 | 25.00 | [a] Estro-Pess [AS] | [a] Vagifem Low [NO] |

#### estradiol valerate 1 mg tablet, 56

| 1663M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 17.51 | 19.05 | Progynova [GH] |

#### estradiol valerate 2 mg tablet, 56

| 1664N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 18.74 | 20.28 | Progynova [GH] |

#### estradiol 2 mg tablet, 56

| 8274L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 20.38 | 21.92 | Zumenon [XT] |

### ESTRADIOL

**Note** Estradiol should be used in conjunction with progestogen in women with an intact uterus.

**estradiol 25 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8311K | | | | | | |
| NP | ‡1 | 5 | 0.00 | 25.54 | 25.00 | Estraderm MX 25 [JU] |

**estradiol 25 microgram/24 hours patch, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14691F | | | | | | |
| NP | ‡1 | 1 | 0.00 | 65.33 | 25.00 | Estramon (Germany, Sandoz) [SZ] |

**estradiol 37.5 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8762E | | | | | | |
| NP | ‡1 | 5 | 0.00 | 30.67 | 25.00 | Estradot 37.5 [SZ] |

**estradiol 50 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8140K | | | | | | |
| NP | ‡1 | 5 | 0.00 | 25.54 | 25.00 | Estraderm MX 50 [JU] |

**estradiol 50 microgram/24 hours patch, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14660N | | | | | | |
| NP | ‡1 | 1 | 0.00 | 62.86 | 25.00 | Estramon (Germany, Sandoz) [SZ] |

**estradiol 75 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8764G | | | | | | |
| NP | ‡1 | 5 | 0.00 | 31.93 | 25.00 | Estradot 75 [SZ] |

**estradiol 75 microgram/24 hours patch, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14652E | | | | | | |
| NP | ‡1 | 1 | 0.00 | 67.08 | 25.00 | Estramon (Germany, Sandoz) [SZ] |

**estradiol 100 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8312L | | | | | | |
| NP | ‡1 | 5 | 0.00 | 27.32 | 25.00 | Estraderm MX 100 [JU] |

**estradiol 100 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8765H | | | | | | |
| NP | ‡1 | 5 | 0.00 | 31.26 | 25.00 | Estradot 100 [SZ] |

**estradiol 100 microgram/24 hours patch, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14715L | | | | | | |
| NP | ‡1 | 1 | 0.00 | 65.05 | 25.00 | Estramon (Germany, Sandoz) [SZ] |

**estradiol 0.06% (750 microgram/actuation) gel, 64 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14719Q | | | | | | |
| NP | ‡1 | 5 | 0.00 | 36.43 | 25.00 | Estrogel [HB] |

**estradiol 0.1% (1 mg/g) gel, 28 x 500 mg sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14653F | | | | | | |
| NP | 1 | 5 | 0.00 | 22.62 | 24.16 | Sandrena [OX] |

**estradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8286D | | | | | | |
| NP | ‡1 | 5 | 0.00 | 26.17 | 25.00 | Sandrena [OX] |

## ESTRADIOL

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**estradiol 10 microgram modified release pessary, 18**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13978Q | | | | | | | |
| NP | 2 | 2 | 0.00 | *46.48 | 25.00 | [a] Estro-Pess [AS] | [a] Vagifem Low [NO] |

**estradiol valerate 1 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13872D | | | | | | |
| NP | 2 | 2 | 0.00 | *20.66 | 22.20 | Progynova [GH] |

**estradiol 2 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13931F NP | 2 | 2 | 0.00 | *26.40 | 25.00 | Zumenon [XT] |

**estradiol valerate 2 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13980T NP | 2 | 2 | 0.00 | *23.12 | 24.66 | Progynova [GH] |

## ESTRADIOL

**Note** Estradiol should be used in conjunction with progestogen in women with an intact uterus.

**Note** Pharmaceutical benefits that have the brand Estradot 25 may be substituted for pharmaceutical benefits that have the brand Dermestril 25 (Italy) in case of shortage.

**estradiol 25 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8761D NP | ‡1 | 5 | 0.00 | 31.35 | 25.00 | [a] Estradot 25 [SZ] |

**estradiol 25 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15524C NP | ‡1 | 5 | 0.00 | 90.00 | 25.00 | [a] Dermestril 25 (Italy) [KQ] |

## ESTRADIOL

**Note** Estradiol should be used in conjunction with progestogen in women with an intact uterus.

**Note** Pharmaceutical benefits that have the brand Estradot 50 may be substituted for pharmaceutical benefits that have the brand Dermestril 50 (Italy) in case of shortage.

**estradiol 50 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8763F NP | ‡1 | 5 | 0.00 | 30.53 | 25.00 | [a] Estradot 50 [SZ] |

**estradiol 50 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15507E NP | ‡1 | 5 | 0.00 | 103.37 | 25.00 | [a] Dermestril 50 (Italy) [KQ] |

## ESTRADIOL

**Note** Estradiol should be used in conjunction with progestogen in women with an intact uterus.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**estradiol 0.06% (750 microgram/actuation) gel, 64 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14741W NP | 2 | 5 | 0.00 | *58.50 | 25.00 | Estrogel [HB] |

**estradiol 0.1% (1 mg/g) gel, 28 x 500 mg sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14642P NP | 2 | 5 | 0.00 | *30.88 | 25.00 | Sandrena [OX] |

**estradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14026F NP | ‡2 | 5 | 0.00 | *37.98 | 25.00 | Sandrena [OX] |

## ESTRIOL

**estriol 500 microgram pessary, 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1771F NP | ‡1 | 2 | 0.00 | 26.78 | 25.00 | Ovestin Ovula [AS] |

**estriol 0.1% (1 mg/g) cream, 15 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1781R NP | ‡1 | 1 | 0.00 | 25.34 | 25.00 | Ovestin [AS] |

## ESTRIOL

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**estriol 500 microgram pessary, 15**

| 14059Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 2 | 0.00 | *39.20 | 25.00 | Ovestin Ovula [AS] |

**estriol 0.1% (1 mg/g) cream, 15 g**

| 13926Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 1 | 0.00 | *36.32 | 25.00 | Ovestin [AS] |

## PROGESTOGENS

### *Pregnen (4) derivatives*

### MEDROXYPROGESTERONE

**medroxyprogesterone acetate 5 mg tablet, 56**

| 2323G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 19.70 | 21.24 | [a] Provera [PF] | [a] Ralovera [FZ] |

**medroxyprogesterone acetate 10 mg tablet, 30**

| 2321E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 21.02 | 22.56 | [a] Ralovera [FZ] | |
| | | | [B]6.50 | 27.52 | 22.56 | [a] Provera [PF] | |

### MEDROXYPROGESTERONE

**Restricted benefit**

***6244***

Endometriosis

**medroxyprogesterone acetate 10 mg tablet, 100**

| 2722G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 36.58 | 25.00 | [a] Ralovera [FZ] | |
| | | | [B]6.49 | 43.07 | 25.00 | [a] Provera [PF] | |

### MEDROXYPROGESTERONE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**medroxyprogesterone acetate 5 mg tablet, 56**

| 13956M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *25.04 | 25.00 | [a] Provera [PF] | [a] Ralovera [FZ] |

**medroxyprogesterone acetate 10 mg tablet, 30**

| 13849X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *27.68 | 25.00 | [a] Ralovera [FZ] | |
| | | | [B]13.00 | *40.68 | 25.00 | [a] Provera [PF] | |

### MEDROXYPROGESTERONE

**Restricted benefit**

***15030***

Endometriosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**medroxyprogesterone acetate 10 mg tablet, 100**

| 13928C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *58.80 | 25.00 | [a] Ralovera [FZ] | |
| | | | [B]12.98 | *71.78 | 25.00 | [a] Provera [PF] | |

### PROGESTERONE

**progesterone 100 mg capsule, 30**

| 14730G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 43.51 | 25.00 | [a] Progesterone ADVZ 100 [BZ] | [a] PROGESTERONE-APX [XT] |
| | | | | | | [a] Prometrium [XW] | |

## PROGESTERONE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**progesterone 100 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14733K NP | 2 | 5 | 0.00 | *72.66 | 25.00 | [a] Progesterone ADVZ 100 [BZ]<br>[a] Prometrium [XW] | [a] PROGESTERONE-APX [XT] |

## PROGESTERONE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***11673***

Prevention of preterm birth

**Clinical criteria:**

- Patient must have a singleton pregnancy, **AND**
- Patient must have at least one of: (i) short cervix (mid-trimester sonographic cervix no greater than 25 mm), (ii) a history of spontaneous preterm birth, **AND**
- The treatment must be administered no earlier than at 16 weeks gestation.

**progesterone 200 mg pessary, 15**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12465C NP MW | 3 | 3 | 0.00 | *125.67 | 25.00 | Oripro [ON] |

## PROGESTERONE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***11835***

Prevention of preterm birth

**Clinical criteria:**

- Patient must have a singleton pregnancy, **AND**
- Patient must have at least one of: (i) short cervix (mid-trimester sonographic cervix no greater than 25 mm), (ii) a history of spontaneous preterm birth, **AND**
- The treatment must be administered no earlier than at 16 weeks gestation.

**progesterone 200 mg pessary, 42**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12598C NP MW | 1 | 3 | 0.00 | 93.14 | 25.00 | [a] Progesterone BNM 200 [BZ] | [a] Utrogestan [HB] |

### *Pregnadien derivatives*

## DIENOGEST

**Authority Required (STREAMLINED)**

***16222***

Endometriosis

**dienogest 2 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14667Y NP | 1 | 5 | 0.00 | 57.28 | 25.00 | [a] Dinasane [XT] | [a] Visanne [BN] |

### *Estren derivatives*

## NORETHISTERONE

**norethisterone 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2993M NP | 1 | 2 | 0.00 | 35.91 | 25.00 | Primolut N [BN] |

## NORETHISTERONE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**norethisterone 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13873E NP | 2 | 2 | 0.00 | *57.46 | 25.00 | Primolut N [BN] |

## PROGESTOGENS AND ESTROGENS IN COMBINATION

### *Progestogens and estrogens, fixed combinations*

### ESTRADIOL + NORETHISTERONE ACETATE

**estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8427M NP | ‡1 | 5 | 0.00 | 36.69 | 25.00 | Estalis continuous 50/140 [SZ] |

**estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8428N NP | ‡1 | 5 | 0.00 | 34.99 | 25.00 | Estalis continuous 50/250 [SZ] |

### ESTRADIOL + NORETHISTERONE ACETATE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13902Q NP | ‡2 | 5 | 0.00 | *59.02 | 25.00 | Estalis continuous 50/140 [SZ] |

**estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14336M NP | ‡2 | 5 | 0.00 | *55.62 | 25.00 | Estalis continuous 50/250 [SZ] |

### PROGESTERONE (&) ESTRADIOL

**progesterone 100 mg capsule [30] (&) estradiol 0.06% (750 microgram/actuation) gel [64 actuations], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14721T NP | ‡1 | 5 | 0.00 | 58.26 | 25.00 | Estrogel Pro [HB] |

### PROGESTERONE (&) ESTRADIOL

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**progesterone 100 mg capsule [30] (&) estradiol 0.06% (750 microgram/actuation) gel [64 actuations], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14720R NP | 2 | 5 | 0.00 | *102.16 | 25.00 | Estrogel Pro [HB] |

### *Progestogens and estrogens, sequential preparations*

### ESTRADIOL (&) ESTRADIOL + DYDROGESTERONE

**estradiol 1 mg tablet [14] (&) estradiol 1 mg + dydrogesterone 10 mg tablet [14], 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10146B NP | ‡1 | 5 | 0.00 | 24.77 | 25.00 | Femoston 1/10 [XT] |

**estradiol 2 mg tablet [14] (&) estradiol 2 mg + dydrogesterone 10 mg tablet [14], 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8244X NP | ‡1 | 5 | 0.00 | 24.77 | 25.00 | Femoston 2/10 [XT] |

### ESTRADIOL (&) ESTRADIOL + DYDROGESTERONE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**estradiol 1 mg tablet [14] (&) estradiol 1 mg + dydrogesterone 10 mg tablet [14], 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14024D NP | ‡2 | 5 | 0.00 | *35.18 | 25.00 | Femoston 1/10 [XT] |

**estradiol 2 mg tablet [14] (&) estradiol 2 mg + dydrogesterone 10 mg tablet [14], 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13930E NP | ‡2 | 5 | 0.00 | *35.18 | 25.00 | Femoston 2/10 [XT] |

## ESTRADIOL (&) ESTRADIOL + NORETHISTERONE ACETATE

**estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8425K NP | ‡1 | 5 | 0.00 | 44.91 | 25.00 | Estalis sequi 50/140 [SZ] |

**estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8426L NP | ‡1 | 5 | 0.00 | 43.29 | 25.00 | Estalis sequi 50/250 [SZ] |

## ESTRADIOL (&) ESTRADIOL + NORETHISTERONE ACETATE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13932G NP | ‡2 | 5 | 0.00 | *75.46 | 25.00 | Estalis sequi 50/140 [SZ] |

**estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13981W NP | ‡2 | 5 | 0.00 | *72.22 | 25.00 | Estalis sequi 50/250 [SZ] |

# GONADOTROPINS AND OTHER OVULATION STIMULANTS

## *Gonadotropins*

## CHORIOGONADOTROPIN ALFA

**Note** Pharmaceutical benefits that have the form choriogonadotropin alfa solution for injection 250 micrograms in 0.5 mL pre-filled syringe (Ovidrel USA) can be substituted for choriogonadotropin alfa solution for injection 250 micrograms in 0.5 mL pre-filled pen in the case of a shortage.

**Restricted benefit**

***14096***

Infertility indications other than that of Assisted Reproductive Technology

**Treatment criteria:**

- Patient must not be undergoing treatment with medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule, **AND**
- Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing, **AND**
- Must be treated by an obstetrician/gynaecologist; **OR**
- Must be treated by a specialist in reproductive endocrinology/infertility; **OR**
- Must be treated by a urogynaecologist; **OR**
- Must be treated by an endocrinologist; **OR**
- Must be treated by a urologist.

The PBS prescription, whether it is to initiate or continue treatment, must be made out under the specialist's prescriber number.

**choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13300B | 4 | 5 | 0.00 | *296.68 | 25.00 | [a] Ovidrel [SG] |

**choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14640M | 4 | 5 | 0.00 | *503.48 | 25.00 | [a] Ovidrel (USA) [SG] |

## FOLLITROPIN ALFA

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form follitropin alfa cartridge (Ovaleap) and pharmaceutical benefits that have the form follitropin alfa single pen device (Gonal-f Pen), in the same corresponding strength, are equivalent for the purposes of substitution.

Where the Ovaleap brand is supplied, the separate pen device is to be supplied to the patient where required as it is not packaged with the cartridges. The pen device for the Ovaleap brand can be obtained by contacting the pharmaceutical wholesaler, or, the sponsor directly.

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**Restricted benefit**

***6257***

Anovulatory infertility

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

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**Restricted benefit**

***6321***

Infertility

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

### follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL pen devices

| 10865W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 1 | 0.00 | *346.50 | 25.00 | Bemfola [FX] |

### follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL pen devices

| 10877L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 1 | 0.00 | *683.70 | 25.00 | Bemfola [FX] |

### follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL pen devices

| 10876K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 1 | 0.00 | *1,020.87 | 25.00 | Bemfola [FX] |

### follitropin alfa 300 units (21.84 microgram)/0.48 mL injection, 0.48 mL pen device

| 8713N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | 0.00 | *293.31 | 25.00 | [a] Gonal-f Pen [SG] |

### follitropin alfa 300 units (22 microgram)/0.5 mL injection, 0.5 mL cartridge

| 12769C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | 0.00 | *293.31 | 25.00 | [a] Ovaleap [TT] |

### follitropin alfa 450 units (32.76 microgram)/0.72 mL injection, 0.72 mL pen device

| 8714P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | 0.00 | *435.24 | 25.00 | [a] Gonal-f Pen [SG] |

### follitropin alfa 450 units (33 microgram)/0.75 mL injection, 0.75 mL cartridge

| 12808D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | 0.00 | *435.24 | 25.00 | [a] Ovaleap [TT] |

### follitropin alfa 900 units (65.52 microgram)/1.44 mL injection, 1.44 mL pen device

| 8715Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *726.64 | 25.00 | [a] Gonal-f Pen [SG] |

### follitropin alfa 900 units (66 microgram)/1.5 mL injection, 1.5 mL cartridge

| 12778M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *726.64 | 25.00 | [a] Ovaleap [TT] |

## FOLLITROPIN BETA

**Restricted benefit**

***6257***

Anovulatory infertility

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

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**Restricted benefit**

***6321***

Infertility

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

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### follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8565T | 3 | 5 | 0.00 | *309.60 | 25.00 | Puregon 300 IU/0.36 mL [AF] |

### follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8566W | 2 | 5 | 0.00 | *399.94 | 25.00 | Puregon 600 IU/0.72 mL [AF] |

### follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8871X | 2 | 5 | 0.00 | *589.98 | 25.00 | Puregon 900 IU/1.08 mL [AF] |

## HUMAN CHORIONIC GONADOTROPHIN

**Restricted benefit**

***6989***

Anovulatory infertility

**Note** Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note** Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

**Note** Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

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**Restricted benefit**

***6987***

Infertility

**Population criteria:**

- Patient must be male.

**Clinical criteria:**

- The condition must be due to hypogonadotrophic hypogonadism.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

---

**Restricted benefit**

***6990***

Infertility

**Population criteria:**

- Patient must be male.

**Clinical criteria:**

- The condition must be associated with isolated luteinising hormone deficiency.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

---

**Restricted benefit**

***6979***

Combined deficiency of human growth hormone and gonadotrophins

**Population criteria:**

- Patient must be male.

**Clinical criteria:**

- Patient must be one in whom the absence of secondary sexual characteristics indicates a lag in maturation.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**

***6995***

Hypogonadism or delayed puberty

**Population criteria:**

- Patient must be male
- Patient must be aged 16 years or older.

**Clinical criteria:**

- Patient must show clinical evidence of the condition, **AND**
- The treatment must not extend beyond 6 months.

**Note** Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12905F | 1 | 5 | 0.00 | 162.60 | 25.00 | Brevactid 1500 I.E [DZ] |

### *Ovulation stimulants, synthetic*

## CLOMIFENE

**Restricted benefit**

***6221***

Anovulatory infertility

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Restricted benefit**

***6240***

Patients undergoing in-vitro fertilisation

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**clomifene citrate 50 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1211R | 1 | 5 | 0.00 | 35.38 | 25.00 | Clomid [VJ] |

## ANTIANDROGENS

### *Antiandrogens, plain*

## CYPROTERONE

**cyproterone acetate 50 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1270W | 2 | 5 | 0.00 | *73.92 | 25.00 | [a] ANTERONE 50 [RW] | [a] Cyproterone Sandoz [HX] |
| NP | | | [B]1.90 | *75.82 | 25.00 | [a] Androcur [GH] | |

**cyproterone acetate 100 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8019C | 1 | 5 | 0.00 | 60.74 | 25.00 | [a] ANTERONE 100 [RW] | [a] Cyproterone Sandoz [HX] |
| NP | | | [B]1.17 | 61.91 | 25.00 | [a] Androcur-100 [GH] | |

## CYPROTERONE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**cyproterone acetate 50 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14023C | 4 | 5 | 0.00 | *134.44 | 25.00 | [a] ANTERONE 50 [RW] | [a] Cyproterone Sandoz [HX] |
| NP | | | [B]4.00 | *138.44 | 25.00 | [a] Androcur [GH] | |

**cyproterone acetate 100 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14022B | 2 | 5 | 0.00 | *107.12 | 25.00 | [a] ANTERONE 100 [RW] | [a] Cyproterone Sandoz [HX] |
| NP | | | [B]2.34 | *109.46 | 25.00 | [a] Androcur-100 [GH] | |

## CYPROTERONE

**Caution** This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

**Authority Required (STREAMLINED)**

***5532***

Moderate to severe androgenisation

**Clinical criteria:**

- The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

**Population criteria:**

- Patient must be female.

**Clinical criteria:**

- Patient must not be pregnant.

**cyproterone acetate 50 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1269T | | | | | | | |
| NP | 1 | 5 | 0.00 | 26.27 | 25.00 | [a] ANTERONE 50 [RW] | [a] Cyproterone Sandoz [HX] |

## CYPROTERONE

**Caution** This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

**Authority Required (STREAMLINED)**

***14868***

Moderate to severe androgenisation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

**Population criteria:**

- Patient must be female.

**Clinical criteria:**

- Patient must not be pregnant.

**cyproterone acetate 50 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13925X | | | | | | | |
| NP | 2 | 5 | 0.00 | *38.18 | 25.00 | [a] ANTERONE 50 [RW] | [a] Cyproterone Sandoz [HX] |

# OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

### *Progesterone receptor modulators*

## MIFEPRISTONE (&) MISOPROSTOL

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***14202***

Termination of an intra-uterine pregnancy

**Clinical criteria:**

- The condition must be an intra-uterine pregnancy of up to 63 days of gestation.

**mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10211K | | | | | | | |
| NP MW | ‡1 | 0 | 0.00 | 380.19 | 25.00 | [a] ARZESTRA [LJ] | [a] MS-2 Step [XH] |

# UROLOGICALS

## UROLOGICALS

### *Drugs for urinary frequency and incontinence*

## OXYBUTYNIN

**Restricted benefit**

***6241***

Detrusor overactivity

**oxybutynin hydrochloride 5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8039D | | | | | | |
| NP | 1 | 5 | 0.00 | 22.93 | 24.47 | Ditropan [SW] |

## OXYBUTYNIN

**Restricted benefit**

***6243***

Detrusor overactivity

**Clinical criteria:**

- Patient must be unable to tolerate oral oxybutynin; **OR**
- Patient must be unable to swallow oral oxybutynin.

**oxybutynin 3.9 mg/24 hours patch, 8**

| 9454N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 39.90 | 25.00 | Oxytrol [TT] |

## OXYBUTYNIN

**Restricted benefit**

***14915***

Detrusor overactivity

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**oxybutynin hydrochloride 5 mg tablet, 100**

| 13957N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *31.50 | 25.00 | Ditropan [SW] |

## OXYBUTYNIN

**Restricted benefit**

***15006***

Detrusor overactivity

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be unable to tolerate oral oxybutynin; **OR**
- Patient must be unable to swallow oral oxybutynin.

**oxybutynin 3.9 mg/24 hours patch, 8**

| 13984B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *65.44 | 25.00 | Oxytrol [TT] |

## PROPANTHELINE

**Restricted benefit**

***6241***

Detrusor overactivity

**propantheline bromide 15 mg tablet, 100**

| 1953T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *25.08 | 25.00 | Pro-Banthine [RW] |

## PROPANTHELINE

**Restricted benefit**

***14915***

Detrusor overactivity

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**propantheline bromide 15 mg tablet, 100**

| 13927B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *35.80 | 25.00 | Pro-Banthine [RW] |

### *Other urologicals*

## BICARBONATE

**sodium bicarbonate 840 mg capsule, 100**

| 9470K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 22.31 | 23.85 | Sodibic [AS] |

## BICARBONATE

**Restricted benefit**

***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**sodium bicarbonate 840 mg capsule, 100**

| 13933H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *30.26 | 25.00 | Sodibic [AS] |

## PHENOXYBENZAMINE

**Restricted benefit**
***16499***
Phaeochromocytoma
**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**Restricted benefit**
***16567***
Neurogenic urinary retention
**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**phenoxybenzamine hydrochloride 10 mg capsule, 30**

| 1166J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *659.16 | 25.00 | Amdipharm Mercury (Australia) Pty Limited [GH] |

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

| 1862B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 731.38 | 25.00 | Dibenyline [GH] |

# DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

## *Alpha-adrenoreceptor antagonists*

## DUTASTERIDE + TAMSULOSIN

**Authority Required (STREAMLINED)**
***6189***
Benign prostatic hyperplasia
**Clinical criteria:**

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia.

**dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30**

| 5490Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 31.73 | 25.00 | [a] Doubluts [GC] | [a] Dutasteride/Tamsulosin Lupin 500/400 [GQ] |
| | | | | | | [a] Dutasteride/Tamsulosin Sandoz 500/400 [SZ] | [a] Dutasteride/Tamsulosin Viatris 500/400 [AF] |
| | | | | | | [a] DUTASTERIDE/TAMSULOSIN-WGR [WG] | [a] DUTASTERIDE-TAMSULOSIN ZPL [CR] |
| | | | | | | [a] DUTATAM 500/400 [TN] | |
| | | | [B]3.39 | 35.12 | 25.00 | [a] Duodart 500ug/400ug [GK] | |

## DUTASTERIDE + TAMSULOSIN

**Authority Required (STREAMLINED)**
***15004***
Benign prostatic hyperplasia
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia.

**dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30**

| 13929D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *49.10 | 25.00 | [a] Doubluts [GC] | [a] Dutasteride/Tamsulosin Lupin 500/400 [GQ] |

| 13929D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Dutasteride/Tamsulosin Sandoz 500/400 [SZ] | [a] Dutasteride/Tamsulosin Viatris 500/400 [AF] |
| | | | | | | [a] DUTASTERIDE/TAMSULOSIN-WGR [WG] | [a] DUTASTERIDE-TAMSULOSIN ZPL [CR] |
| | | | | | | [a] DUTATAM 500/400 [TN] | |
| | | | [B]6.78 | 55.88 | 25.00 | [a] Duodart 500ug/400ug [GK] | |

### *Testosterone-5-alpha reductase inhibitors*

## DUTASTERIDE

**Authority Required (STREAMLINED)**

***6202***

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia, **AND**
- The treatment must be in combination with an alpha-antagonist.

**dutasteride 500 microgram capsule, 30**

| 5468T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 30.23 | 25.00 | [a] APO-Dutasteride [TX] | [a] Dutacor [CR] |
| | | | [B]6.79 | 37.02 | 25.00 | [a] Avodart [GK] | |

## DUTASTERIDE

**Authority Required (STREAMLINED)**

***15018***

Benign prostatic hyperplasia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia, **AND**
- The treatment must be in combination with an alpha-antagonist.

**dutasteride 500 microgram capsule, 30**

| 13900N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *46.10 | 25.00 | [a] APO-Dutasteride [TX] | [a] Dutacor [CR] |
| | | | [B]13.58 | *59.68 | 25.00 | [a] Avodart [GK] | |

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

# PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

## ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

### *ACTH*

## TETRACOSACTIDE

**Restricted benefit**

***7484***

Hypsarrhythmia and/or infantile spasms

**tetracosactide 1 mg/mL modified release injection, 1 mL ampoule**

| 2832C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 5 | 5 | 0.00 | *300.69 | 25.00 | Synacthen Depot 1 mg/1 mL [IX] |

### *Thyrotropin*

## THYROTROPIN ALFA

**Restricted benefit**

***5296***

Ablation of thyroid remnant tissue

**Clinical criteria:**

- Patient must have undergone a thyroidectomy, **AND**
- The treatment must be in combination with radioactive iodine, **AND**
- Patient must not have a known metastatic disease.

**thyrotropin alfa 900 microgram injection, 2 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2700D | 1 | 0 | 0.00 | 1,560.27 | 25.00 | Thyrogen [GZ] |

## POSTERIOR PITUITARY LOBE HORMONES

### *Vasopressin and analogues*

### DESMOPRESSIN

**Authority Required (STREAMLINED)**

***5266***

Cranial diabetes insipidus

**desmopressin acetate 200 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8662X | 3 | 5 | 0.00 | *111.03 | 25.00 | Minirin [FP] |

### DESMOPRESSIN

**Authority Required (STREAMLINED)**

***15012***

Cranial diabetes insipidus

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**desmopressin acetate 200 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13889B | 6 | 5 | 0.00 | *212.34 | 25.00 | Minirin [FP] |

### DESMOPRESSIN

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations; and
- desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations.

**Authority Required (STREAMLINED)**

***5266***

Cranial diabetes insipidus

**desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8711L | 2 | 5 | 0.00 | *100.50 | 25.00 | [a] Minirin Nasal Spray [FP] |

**desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15282H | 2 | 5 | 0.00 | *86.14 | 25.00 | [a] Desmomed [DZ] |

### DESMOPRESSIN

**Authority Required (STREAMLINED)**

***5413***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.

**Authority Required (STREAMLINED)**

***5295***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.

**desmopressin acetate 200 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8663Y NP | 1 | 5 | 0.00 | 46.58 | 25.00 | Minirin [FP] |

## DESMOPRESSIN

**Authority Required (STREAMLINED)**

***14972***

Primary nocturnal enuresis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

No more than twice the maximum quantity will be authorised.

**Note** Not to be used in preference to enuresis alarms.

**Authority Required (STREAMLINED)**

***14842***

Primary nocturnal enuresis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

No more than twice the maximum quantity will be authorised.

**Note** Not to be used in preference to enuresis alarms.

**desmopressin acetate 200 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13945Y NP | 2 | 5 | 0.00 | *78.80 | 25.00 | Minirin [FP] |

## DESMOPRESSIN

**Caution** Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations; and
- desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations.

**Authority Required (STREAMLINED)**

***5342***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Caution** Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

**Note** Not to be used in preference to enuresis alarms.

**Authority Required (STREAMLINED)**

***5267***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**Caution** Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

**Note** Not to be used in preference to enuresis alarms.

**desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8712M | ‡1 | 5 | 0.00 | 57.43 | 25.00 | [a] Minirin Nasal Spray [FP] |
| NP | | | | | | |

**desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15333B | ‡1 | 5 | 0.00 | 50.25 | 25.00 | [a] Desmomed [DZ] |
| NP | | | | | | |

## DESMOPRESSIN

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- Desmopressin 240 microgram sublingual tablet; and
- Desmopressin 240 microgram sublingual wafer.

**Authority Required (STREAMLINED)**

***5412***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

**Authority Required (STREAMLINED)**

***5226***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

**desmopressin 240 microgram sublingual wafer, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8975J | 1 | 5 | 0.00 | 75.38 | 25.00 | [a] Minirin Melt [FP] |
| NP | | | | | | |

**Desmopressin 240 microgram sublingual tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15291T | 1 | 5 | 0.00 | 75.38 | 25.00 | [a] Desmopressin ADVZ [BZ] |
| NP | | | | | | |

## DESMOPRESSIN

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- Desmopressin 120 microgram sublingual tablet; and
- Desmopressin 120 microgram sublingual wafer.

**Authority Required (STREAMLINED)**

***5412***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

**Authority Required (STREAMLINED)**

***5226***

Primary nocturnal enuresis

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

**Note** Not to be used in preference to enuresis alarms.

**Note** Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

### desmopressin 120 microgram sublingual wafer, 30

| 9398P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 50.26 | 25.00 | [a] Minirin Melt [FP] |

### Desmopressin 120 microgram sublingual tablet, 30

| 15313Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 50.26 | 25.00 | [a] Desmopressin ADVZ [BZ] |

## DESMOPRESSIN

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- Desmopressin 240 microgram sublingual tablet; and
- Desmopressin 240 microgram sublingual wafer.

**Authority Required (STREAMLINED)**

***14945***

Primary nocturnal enuresis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

No increase in the maximum quantity or number of units may be authorised.

**Note** Not to be used in preference to enuresis alarms.

**Authority Required (STREAMLINED)**

***15025***

Primary nocturnal enuresis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

No increase in the maximum quantity or number of units may be authorised.

**Note** Not to be used in preference to enuresis alarms.

### desmopressin 240 microgram sublingual wafer, 30

| 13890C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *137.50 | 25.00 | [a] Minirin Melt [FP] |

### Desmopressin 240 microgram sublingual tablet, 30

| 15312X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *137.50 | 25.00 | [a] Desmopressin ADVZ [BZ] |

## DESMOPRESSIN

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- Desmopressin 120 microgram sublingual tablet; and
- Desmopressin 120 microgram sublingual wafer.

**Authority Required (STREAMLINED)**

***14972***

Primary nocturnal enuresis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be refractory to an enuresis alarm.

No more than twice the maximum quantity will be authorised.

**Note** Not to be used in preference to enuresis alarms.

**Authority Required (STREAMLINED)**

***14842***

Primary nocturnal enuresis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be 6 years of age or older.

**Clinical criteria:**

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

No more than twice the maximum quantity will be authorised.

**Note** Not to be used in preference to enuresis alarms.

**desmopressin 120 microgram sublingual wafer, 30**

| 14004C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *86.16 | 25.00 | [a] Minirin Melt [FP] |

**Desmopressin 120 microgram sublingual tablet, 30**

| 15323L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *86.16 | 25.00 | [a] Desmopressin ADVZ [BZ] |

## HYPOTHALAMIC HORMONES

### *Gonadotropin-releasing hormones*

## NAFARELIN

**Restricted benefit**

***6552***

Endometriosis

Treatment Phase: Initial treatment, for up to 6 months

**Clinical criteria:**

- The condition must be visually proven.

**Restricted benefit**

***6517***

Endometriosis

Treatment Phase: Subsequent treatment, for up to 6 months

**Clinical criteria:**

- The condition must be visually proven, **AND**
- The treatment must not be within 2 years of the end of the previous course of treatment with this drug, **AND**
- Patient must have had a recent bone density assessment.

The date of the bone density assessment must be recorded in the patient's medical records.

**nafarelin 200 microgram/actuation nasal spray, 60 actuations**

| 2962X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 5 | 0.00 | 121.72 | 25.00 | Synarel [PF] |

### *Anti-gonadotropin-releasing hormones*

## RELUGOLIX + ESTRADIOL + NORETHISTERONE ACETATE

**Caution** Ryeqo should not be used interchangeably with GnRH agonists and/or hormonal contraceptives brands due to differences in dose and schedule of treatment.

**Authority Required (STREAMLINED)**

***16429***

Endometriosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have experienced moderate to severe pain associated with endometriosis, **AND**
- The condition must be visually proven, **AND**

- Patient must have received an inadequate response to, or be intolerant to, previous first line therapies for this condition, including at least one of the following: (i) hormonal contraceptives, (ii) analgesics, **AND**
- Patient must not have undergone surgery for this condition in the last 3 months; **OR**
- Patient must not commence this treatment until 3 months post-surgery, **AND**
- Patient must not have a history of, nor currently have any of the following: (i) osteoporosis, (ii) risk of other metabolic bone disease.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner with experience in the diagnosis and management of endometriosis.

**Population criteria:**

- Patient must be pre-menopausal
- Patient must be at least 18 years of age.

Assessment of bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA) is recommended at baseline, after the first 52 weeks of treatment, and annually thereafter. Depending on the degree of change in BMD, the benefit and risks of Ryeqo may need to be reconsidered. Use is recommended to be limited to 24 months, with extension of therapy conditional on stability of DXA and reassessment of risk/benefit in the individual patient by the treating physician.

**Authority Required (STREAMLINED)**

***16430***

Endometriosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have undergone surgery for this condition in the last 3 months, **AND**
- Patient must not have a history of, nor currently have any of the following: (i) osteoporosis, (ii) risk of other metabolic bone disease.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner with experience in the diagnosis and management of endometriosis.

**Population criteria:**

- Patient must be pre-menopausal.

The prescriber must only request for this treatment phase for the patient if ongoing treatment with this drug is likely to result in an adequate response.

Details of bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA) for continuing treatment beyond 6 months if under 41 years of age must be documented in the patient's medical record.

Assessment of bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA) is recommended at baseline, after the first 52 weeks of treatment, and annually thereafter. Depending on the degree of change in BMD, the benefit and risks of Ryeqo may need to be reconsidered. Use is recommended to be limited to 24 months, with extension of therapy conditional on stability of DXA and reassessment of risk/benefit in the individual patient by the treating physician.

**relugolix 40 mg + estradiol 1 mg + norethisterone acetate 500 microgram tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14795Q | 1 | 5 | 0.00 | 208.18 | 25.00 | Ryeqo [FX] |

# CORTICOSTEROIDS FOR SYSTEMIC USE

## CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN

### *Mineralocorticoids*

### FLUDROCORTISONE

**Restricted benefit**

***16559***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**fludrocortisone acetate 100 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1433K NP | 2 | 1 | 0.00 | *35.38 | 25.00 | [a] Florinef [AS] | [a] FLUDROCORTISONE MEDSURGE [DZ] |

### *Glucocorticoids*

### ABIRATERONE (&) METHYLPREDNISOLONE

**Caution** The bioavailability on a mg to mg basis of abiraterone combination product Yonsa MPred to ANDRIGA-10 or abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***17939***

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); **OR**
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [60], 1 pack**

| 13263C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | 0.00 | 682.85 | 25.00 | Yonsa Mpred [RA] |

## ABIRATERONE (&) METHYLPREDNISOLONE

**Caution** The bioavailability on a mg to mg basis of abiraterone combination product Yonsa MPred to ANDRIGA-10 or abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17877***

Metastatic castration sensitive carcinoma of the prostate

**Clinical criteria:**

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); **OR**
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**Treatment criteria:**

- Patient must be undergoing concurrent androgen deprivation therapy, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [30], 1 pack**

| 14078Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 570.97 | 25.00 | Yonsa Mpred [RA] |

## BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE

**Restricted benefit**

***6209***

Local intra-articular or peri-articular infiltration

**Restricted benefit**

***6237***

Keloid

**Restricted benefit**

***6291***

Lichen planus hypertrophic

**betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules**

| 5034Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 30.04 | 25.00 | Celestone Chronodose [OQ] |

## BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE

**Restricted benefit**

***6253***

Alopecia areata

**Restricted benefit**

***6268***

Local intra-articular or peri-articular infiltration

**Restricted benefit**

***6254***

Granulomata

**Clinical criteria:**

- The condition must be dermal.

**Restricted benefit**

***6210***

Keloid

**Restricted benefit**

***6281***

Lichen planus hypertrophic

**Restricted benefit**

***6255***

Lichen simplex chronicus

**Restricted benefit**

***6211***

Chronic discoid lupus erythematosus

**Restricted benefit**

***6269***

Necrobiosis lipoidica

**Restricted benefit**

***6212***

Uveitis

**betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules**

| 2694T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 30.04 | 25.00 | Celestone Chronodose [OQ] |

## CORTISONE

**Restricted benefit**

***16559***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**cortisone acetate 5 mg tablet, 50**

| 1246N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 4 | 0.00 | 21.47 | 23.01 | Cortate [AS] |

**cortisone acetate 25 mg tablet, 60**

| 1247P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 4 | 0.00 | 26.45 | 25.00 | Cortate [AS] |

## CORTISONE

**Restricted benefit**

***16508***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**cortisone acetate 5 mg tablet, 50**

| 13946B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *28.58 | 25.00 | Cortate [AS] |

**cortisone acetate 25 mg tablet, 60**

| 13862N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *38.54 | 25.00 | Cortate [AS] |

## DEXAMETHASONE

**dexamethasone 500 microgram tablet, 30**

| 1292B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 4 | 0.00 | 17.10 | 18.64 | Dexmethsone [AS] |

**dexamethasone 4 mg tablet, 30**

| 2507Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 4 | 0.00 | 19.44 | 20.98 | Dexmethsone [AS] |

## DEXAMETHASONE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**dexamethasone 500 microgram tablet, 30**

| 14007F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *19.84 | 21.38 | Dexmethsone [AS] |

## HYDROCORTISONE

**Restricted benefit**

***16559***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**hydrocortisone 4 mg tablet, 50**

| 1499X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 4 | 0.00 | 28.39 | 25.00 | [a] Hydrocortisone Viatris 4 [AL] | |
| | | | [B]2.91 | 31.30 | 25.00 | [a] Hysone 4 [AF] | |

**hydrocortisone 20 mg tablet, 60**

| 1500Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 4 | 0.00 | 34.39 | 25.00 | [a] Hydrocortisone Viatris 20 [AL] | |
| | | | [B]2.91 | 37.30 | 25.00 | [a] Hysone 20 [AF] | |

## HYDROCORTISONE

**Restricted benefit**

***16508***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**hydrocortisone 4 mg tablet, 50**

| 13863P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *42.42 | 25.00 | [a] Hydrocortisone Viatris 4 [AL] | |
| | | | [B]5.82 | *48.24 | 25.00 | [a] Hysone 4 [AF] | |

**hydrocortisone 20 mg tablet, 60**

| 14476X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *54.42 | 25.00 | [a] Hydrocortisone Viatris 20 [AL] | |
| | | | [B]5.82 | *60.24 | 25.00 | [a] Hysone 20 [AF] | |

## HYDROCORTISONE SODIUM SUCCINATE

**hydrocortisone (as sodium succinate) 100 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1501B | | | | | | |
| NP | 2 | 0 | 0.00 | *25.02 | 25.00 | Solu-Cortef [PF] |

**hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3096Y | | | | | | |
| NP | 1 | 0 | 0.00 | 23.66 | 25.00 | Solu-Cortef [PF] |

## HYDROCORTISONE SODIUM SUCCINATE

**Restricted benefit**

***6252***

For use in a hospital

**hydrocortisone (as sodium succinate) 100 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1510L | | | | | | |
| NP | 6 | 0 | 0.00 | *46.32 | 25.00 | Solu-Cortef [PF] |

**hydrocortisone (as sodium succinate) 100 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5118J | | | | | | |
| DP | 6 | 0 | 0.00 | *46.32 | 25.00 | Solu-Cortef [PF] |

**hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1511M | | | | | | |
| NP | 6 | 0 | 0.00 | *70.14 | 25.00 | Solu-Cortef [PF] |

**hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5119K | | | | | | |
| DP | 6 | 0 | 0.00 | *70.14 | 25.00 | Solu-Cortef [PF] |

## METHYLPREDNISOLONE

**Restricted benefit**

***6273***

Local intra-articular or peri-articular infiltration

**methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1928L | | | | | | |
| NP | 1 | 0 | 0.00 | 28.57 | 25.00 | Depo-Medrol [PF] |

## METHYLPREDNISOLONE

**Restricted benefit**

***6209***

Local intra-articular or peri-articular infiltration

**methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5148Y | | | | | | |
| DP | 1 | 0 | 0.00 | 28.57 | 25.00 | Depo-Medrol [PF] |

## PREDNISOLONE

**prednisolone 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3152X | | | | | | | |
| NP | 1 | 4 | 0.00 | 17.48 | 19.02 | [a] Predsolone [LN] | |
| | | | [B]0.93 | 18.41 | 19.02 | [a] Panafcortelone [AS] | |

**prednisolone 5 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1917X | | | | | | | |
| NP | 1 | 4 | 0.00 | 17.89 | 19.43 | Panafcortelone [AS] | Solone [IL] |

**prednisolone 25 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1916W | | | | | | | |
| NP | 1 | 4 | 0.00 | 18.58 | 20.12 | Panafcortelone [AS] | Solone [IL] |

## PREDNISOLONE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**prednisolone 1 mg tablet, 100**

| 13888Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *20.60 | 22.14 | [a] Predsolone [LN] | |
| | | | [B]1.86 | *22.46 | 22.14 | [a] Panafcortelone [AS] | |

**prednisolone 5 mg tablet, 60**

| 14045F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *21.42 | 22.96 | Panafcortelone [AS] | Solone [IL] |

## PREDNISOLONE SODIUM PHOSPHATE

**prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL**

| 8285C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 20.56 | 22.10 | [a] PredMix [LN] | |
| | | | [B]2.01 | 22.57 | 22.10 | [a] Redipred [AS] | |

## PREDNISOLONE SODIUM PHOSPHATE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL**

| 13837G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *26.76 | 25.00 | [a] PredMix [LN] | |
| | | | [B]4.02 | *30.78 | 25.00 | [a] Redipred [AS] | |

## PREDNISONE

**prednisone 1 mg tablet, 100**

| 1934T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 4 | 0.00 | 17.43 | 18.97 | [a] Predsone [LN] | |
| | | | [B]0.93 | 18.36 | 18.97 | [a] Panafcort [AS] | |

**prednisone 5 mg tablet, 60**

| 1935W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 4 | 0.00 | 17.81 | 19.35 | Panafcort [AS] | Sone [IL] |

**prednisone 25 mg tablet, 30**

| 1936X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 4 | 0.00 | 17.37 | 18.91 | Panafcort [AS] | Sone [IL] |

## PREDNISONE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**prednisone 1 mg tablet, 100**

| 14043D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *20.50 | 22.04 | [a] Predsone [LN] | |
| | | | [B]1.86 | *22.36 | 22.04 | [a] Panafcort [AS] | |

**prednisone 5 mg tablet, 60**

| 13944X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *21.26 | 22.80 | Panafcort [AS] | Sone [IL] |

## TRIAMCINOLONE

**Restricted benefit**

***6209***

Local intra-articular or peri-articular infiltration

**Restricted benefit**

***6237***

Keloid

**Restricted benefit**

***6291***

Lichen planus hypertrophic

**triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules**

| 5233K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 30.04 | 25.00 | Kenacort-A10 [AS] |

## TRIAMCINOLONE

**Restricted benefit**

***6253***

Alopecia areata

**Restricted benefit**

***6268***

Local intra-articular or peri-articular infiltration

**Restricted benefit**

***6254***

Granulomata

**Clinical criteria:**

- The condition must be dermal.

**Restricted benefit**

***6210***

Keloid

**Restricted benefit**

***6281***

Lichen planus hypertrophic

**Restricted benefit**

***6255***

Lichen simplex chronicus

**Restricted benefit**

***6211***

Chronic discoid lupus erythematosus

**Restricted benefit**

***6269***

Necrobiosis lipoidica

**Restricted benefit**

***6287***

Psoriasis

**triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules**

| 2990J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 30.04 | 25.00 | Kenacort-A10 [AS] |

# ANTIADRENAL PREPARATIONS

## *Anticorticosteroids*

## OSILODROSTAT

**Caution** The following should be assessed prior to receiving treatment and closely monitored throughout the treatment period:

1. QTc prolongation via an electrocardiogram
2. Hypocortisolism
3. Corticotroph tumour growth

**Note** Cortisol levels should be monitored at regular intervals, since hypocortisolism-related events can occur at any time during treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16306***

Endogenous Cushing's syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be at least one of: (i) persistent hypercortisolism after surgery, (ii) recurrent hypercortisolism after surgery, (iii) inappropriate for surgery, **AND**
- Patient must have active endogenous Cushing's Syndrome determined by a mean urinary free cortisol (UFC) level greater than 1.3 times the upper limit of normal (ULN); **OR**

- Patient must have undergone treatment for this condition with conventional therapies to control cortisol production resulting in an improved UFC level prior to applying for the initial authority application of this drug.

**Treatment criteria:**

- Must be treated by an endocrinologist.

**Population criteria:**

- Patient must be at least 18 years of age.

For the purposes of administering this restriction, the mean UFC is the average of at least two values being 1.3 times greater than the ULN.

Patient must undergo a dose titration period whereby responses must be assessed every 1-2 weeks until the mean UFC levels are within the normal range.

At the time of authority application, medical practitioners must request the appropriate number of packs to provide sufficient drug, based on the prescribed dose of the patient, for 4 weeks of treatment.

A separate authority prescription form must be completed for each strength requested. The dose must not exceed 30 mg twice daily. Up to a maximum of 6 repeats will be authorised.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the dose is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

The condition is inappropriate for surgery if the patient:

(i) has a medical contraindication for surgery;

(ii) has inoperable tumours;

(iii) has been determined that surgery is unlikely to reduce hypercortisolism;

(iv) refuses surgery;

(v) cannot access surgical treatment.

**osilodrostat 1 mg tablet, 60**

| 14714K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 6 | 0.00 | 2,580.36 | 25.00 | Isturisa [RJ] |

**osilodrostat 5 mg tablet, 60**

| 14724Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 6 | 0.00 | 9,985.56 | 25.00 | Isturisa [RJ] |

## OSILODROSTAT

**Caution** The following should be assessed prior to receiving treatment and closely monitored throughout the treatment period:

1. QTc prolongation via an electrocardiogram
2. Hypocortisolism
3. Corticotroph tumour growth

**Note** Cortisol levels should be monitored at regular intervals, since hypocortisolism-related events can occur at any time during treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16317***

Endogenous Cushing's syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a complete response after at least 26 weeks of treatment with this drug; **OR**
- Patient must have demonstrated a partial response after at least 26 weeks of treatment with this drug.

**Treatment criteria:**

- Must be treated by an endocrinologist.

**Population criteria:**

- Patient must be at least 18 years of age.

For the purposes of administering this restriction, a complete response is defined as a mean urinary free cortisol (UFC) level of less than or equal to the upper limit of normal (ULN).

A partial response is defined as mean UFC level of greater than ULN but with at least 50% reduction from the baseline value. The mean UFC should be the average of at least two urine samples.

At the time of authority application, medical practitioners must request the appropriate number of packs to provide sufficient drug, based on the prescribed dose of the patient, for 4 weeks of treatment.

A separate authority prescription form must be completed for each strength requested. The dose must not exceed 30 mg twice daily. Up to a maximum of 5 repeats will be authorised.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the dose is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

An application for the continuing treatment must be accompanied with the assessment of response conducted after 26 weeks from the first dose of osilodrostat and no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for patients who meet the continuing restriction for PBS-subsidised treatment.

**osilodrostat 1 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14723X | 1 | 5 | 0.00 | 2,580.36 | 25.00 | Isturisa [RJ] |

**osilodrostat 5 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14729F | 1 | 5 | 0.00 | 9,985.56 | 25.00 | Isturisa [RJ] |

# THYROID THERAPY

## THYROID PREPARATIONS

### *Thyroid hormones*

### LEVOTHYROXINE

**Restricted benefit**

***16261***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

**levothyroxine sodium 125 microgram tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12830G NP MW | 1 | 1 | 0.00 | 24.24 | 25.00 | Eltroxin [LT] |

### LEVOTHYROXINE

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

**Restricted benefit**

***16261***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

**levothyroxine sodium 75 microgram tablet, 2 x 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12960D NP MW | 1 | 1 | 0.00 | 21.91 | 23.45 | [a] LEVOXINE [RA] | [a] Thyrox [IX] |

### LEVOTHYROXINE

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

**Restricted benefit**

***16261***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

**levothyroxine sodium 100 microgram tablet, 2 x 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12968M NP MW | 1 | 1 | 0.00 | 22.06 | 23.60 | [a] LEVOXINE [RA] | [a] Thyrox [IX] |

## LEVOTHYROXINE

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

**Restricted benefit**

***16261***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

### levothyroxine sodium 50 microgram tablet, 2 x 100

| 12969N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 21.79 | 23.33 | [a] LEVOXINE [RA] | [a] Thyrox [IX] |

## LEVOTHYROXINE

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

**Restricted benefit**

***16261***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

### levothyroxine sodium 200 microgram tablet, 2 x 100

| 12970P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 23.38 | 24.92 | [a] LEVOXINE [RA] | [a] Thyrox [IX] |

## LEVOTHYROXINE

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 200 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

**Restricted benefit**

***16261***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

### levothyroxine sodium 200 microgram tablet, 200

| 2173J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 0.00 | 23.38 | 24.92 | [a] APO-Levothyroxine [XT] | [a] Eutroxsig [LN] |
| | | | | | | [a] Levothyroxine Lup [GQ] | [a] Levothyroxine Sandoz [SZ] |
| | | | | | | [b] Eltroxin [LT] | [b] Levothox [AF] |
| | | | [B]0.96 | 24.34 | 24.92 | [a] Oroxine [AS] | |

## LEVOTHYROXINE

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 50 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

**Restricted benefit**

***16261***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

### levothyroxine sodium 50 microgram tablet, 200

| 2174K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 0.00 | 21.79 | 23.33 | [a] APO-Levothyroxine [XT] | [a] Eutroxsig [LN] |
| | | | | | | [a] Levothyroxine Lup [GQ] | [a] Levothyroxine Sandoz [SZ] |
| | | | | | | [b] Eltroxin [LT] | [b] Levothox [AF] |
| | | | [B]0.96 | 22.75 | 23.33 | [a] Oroxine [AS] | |

## LEVOTHYROXINE

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 100 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

**Restricted benefit**

***16261***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

### levothyroxine sodium 100 microgram tablet, 200

| 2175L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 0.00 | 22.06 | 23.60 | [a] APO-Levothyroxine [XT] | [a] Eutroxsig [LN] |
| | | | | | | [a] Levothyroxine Lup [GQ] | [a] Levothyroxine Sandoz [SZ] |
| | | | | | | [b] Eltroxin [LT] | [b] Levothox [AF] |
| | | | [B]0.96 | 23.02 | 23.60 | [a] Oroxine [AS] | |

## LEVOTHYROXINE

**Note** Eltroxin and Levothox are not interchangeable with Oroxine, Eutroxsig, Levoxine, Levothyroxine Lup, APO-Levothyroxine, Thyrox or Levothyroxine Sandoz on a dose to dose basis, and dose titration may be required.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eltroxin and Levothox brands) are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 200 (Eutroxsig, Oroxine, Levothyroxine Lup, APO-Levothyroxine and Levothyroxine Sandoz brands) and pharmaceutical benefits that have the form levothyroxine sodium 75 microgram tablet, 2 x 100 (Levoxine and Thyrox brands) are equivalent for the purposes of substitution.

**Restricted benefit**

***16261***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is each of: (a) sharing patient care with a medical practitioner for the current pregnancy episode, (b) continuing existing treatment with this drug that was initiated by a medical practitioner.

### levothyroxine sodium 75 microgram tablet, 200

| 9287T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 0.00 | 21.91 | 23.45 | [a] APO-Levothyroxine [XT] | [a] Eutroxsig [LN] |
| | | | | | | [a] Levothyroxine Lup [GQ] | [a] Levothyroxine Sandoz [SZ] |
| | | | | | | [b] Eltroxin [LT] | [b] Levothox [AF] |
| | | | [B]0.97 | 22.88 | 23.45 | [a] Oroxine [AS] | |

## LIOTHYRONINE

**Authority Required (STREAMLINED)**

***6475***

Hypothyroidism

**Clinical criteria:**

- The condition must be severe hypothyroidism, **AND**
- The treatment must be for initiation of therapy only.

**liothyronine sodium 20 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14841D | 1 | 2 | 0.00 | 57.32 | 25.00 | Tertroxin [AS] |

## LIOTHYRONINE

**Authority Required (STREAMLINED)**

***16607***

Thyroid cancer

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**Authority Required (STREAMLINED)**

***16676***

Hypothyroidism

**Clinical criteria:**

- The treatment must be for replacement therapy, **AND**
- Patient must have documented intolerance to levothyroxine sodium; **OR**
- Patient must have documented resistance to levothyroxine sodium.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**liothyronine sodium 20 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2318B NP | 1 | 2 | 0.00 | 57.32 | 25.00 | Tertroxin [AS] |

## LIOTHYRONINE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16698***

Thyroid cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**Authority Required (STREAMLINED)**

***16510***

Hypothyroidism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for replacement therapy, **AND**
- Patient must have documented intolerance to levothyroxine sodium; **OR**
- Patient must have documented resistance to levothyroxine sodium.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**liothyronine sodium 20 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13966C NP | 2 | 2 | 0.00 | *100.28 | 25.00 | Tertroxin [AS] |

## ANTITHYROID PREPARATIONS

### *Thiouracils*

## PROPYLTHIOURACIL

**Restricted benefit**

***16559***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**propylthiouracil 50 mg tablet, 100**

| 1955X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *44.88 | 25.00 | PTU [FF] |

## PROPYLTHIOURACIL

**Restricted benefit**

***16508***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**propylthiouracil 50 mg tablet, 100**

| 13836F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *75.40 | 25.00 | PTU [FF] |

### *Sulfur-containing imidazole derivatives*

## CARBIMAZOLE

**Restricted benefit**

***16559***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**carbimazole 5 mg tablet, 100**

| 1153Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *25.70 | 25.00 | [a] Neo-Mercazole [GH] | [a] THIRAZOL [NB] |
| | | | | | | [a] WP Carbimazole [TN] | |

## CARBIMAZOLE

**Restricted benefit**

***16508***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**carbimazole 5 mg tablet, 100**

| 13967D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *37.04 | 25.00 | [a] Neo-Mercazole [GH] | [a] THIRAZOL [NB] |
| | | | | | | [a] WP Carbimazole [TN] | |

# PANCREATIC HORMONES

## GLYCOGENOLYTIC HORMONES

### *Glycogenolytic hormones*

## GLUCAGON HYDROCHLORIDE

**glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

| 1449G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 50.88 | 25.00 | GlucaGen Hypokit [NO] |

**glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

| 5105Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 50.88 | 25.00 | GlucaGen Hypokit [NO] |

# CALCIUM HOMEOSTASIS

## PARATHYROID HORMONES AND ANALOGUES

### *Parathyroid hormones and analogues*

## ABALOPARATIDE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18926***

Severe established osteoporosis

Treatment Phase: Initial treatment - Second-line therapy

**Treatment criteria:**

- Must be treated by a consultant physician.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with any of: (i) teriparatide, (ii) romosozumab or (iii) abaloparatide; **OR**
- Patient must have developed intolerance to (i) teriparatide, or (ii) romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy, **AND**
- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months of PBS and non-PBS-subsidised therapy with this drug for this condition.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

**Authority Required**

***19037***

Severe established osteoporosis

Treatment Phase: Continuing treatment - Second-line therapy

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy, **AND**
- The treatment must not exceed a lifetime maximum of 18 months of PBS and non-PBS-subsidised therapy with this drug for this condition.

### Abaloparatide 2 mg/mL injection, 1.5 mL pen device

15436K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 387.19 | 25.00 | Eladynos [TT] |

## ABALOPARATIDE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**

***18973***

Severe established osteoporosis

Treatment Phase: Initial treatment - First-line therapy

**Treatment criteria:**

- Must be treated by a consultant physician.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with any of: (i) anti-resorptive therapy, (ii) teriparatide, (iii) romosozumab, or (iv) abaloparatide; **OR**
- Patient must have developed intolerance to romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy, **AND**
- Patient must be at very high risk of fracture, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must have had a symptomatic fracture due to minimal trauma, **AND**
- Patient must have had at least 1 hip or symptomatic vertebral fracture in the previous 24 months; **OR**
- Patient must have had at least 2 fractures including 1 symptomatic new fracture in the previous 24 months, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months of PBS and non-PBS-subsidised therapy with this drug for this condition.

Details of fracture history including the date(s), site(s), the symptoms associated with the fracture(s) and the score of the qualifying BMD measurement must be provided at the time of application.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Anti-resorptive therapies for osteoporosis include alendronate sodium, risedronate sodium, raloxifene hydrochloride, denosumab and zoledronic acid.

**Authority Required**

***18997***

Severe established osteoporosis

Treatment Phase: Continuing treatment - First-line therapy

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition as first-line therapy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months of PBS and non-PBS-subsidised therapy with this drug for this condition.

### Abaloparatide 2 mg/mL injection, 1.5 mL pen device

15468D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 387.19 | 25.00 | Eladynos [TT] |

## TERIPARATIDE

**Note** Pharmaceutical benefits that have the form teriparatide 250 microgram/mL injection, 2.4 mL cartridge and the pharmaceutical benefits that have the form teriparatide 250 microgram/mL injection, 2.4 mL pen device are equivalent for the purposes of substitution.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15536***

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Treatment criteria:**

- Must be treated by a specialist; **OR**
- Must be treated by a consultant physician.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

**teriparatide 250 microgram/mL injection, 2.4 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14482F | 2 | 2 | 0.00 | *336.92 | 25.00 | [a] Teriparatide Lupin [GQ] | [a] Terrosa [FX] |

**teriparatide 250 microgram/mL injection, 2.4 mL cartridge**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15188J | 2 | 2 | 0.00 | *336.92 | 25.00 | [a] Ritosa [XT] |

## TERIPARATIDE

**Note** Pharmaceutical benefits that have the form teriparatide 250 microgram/mL injection, 2.4 mL cartridge and the pharmaceutical benefits that have the form teriparatide 250 microgram/mL injection, 2.4 mL pen device are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***19012***

Severe established osteoporosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist; **OR**
- Must be treated by a consultant physician.

**Clinical criteria:**

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy, **AND**
- Patient must not have received PBS-subsidised treatment with any of: (i) romosozumab, (ii) abaloparatide; **OR**
- Patient must have developed intolerance to: (i) romosozumab, or (ii) abaloparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be documented in the patient's medical record.

**Authority Required (STREAMLINED)**

***12270***

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Treatment criteria:**

- Must be treated by a specialist; **OR**
- Must be treated by a consultant physician.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

**teriparatide 250 microgram/mL injection, 2.4 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14093R | 1 | 5 | 0.00 | 173.14 | 25.00 | [a] Teriparatide Lupin [GQ] | [a] Terrosa [FX] |

**teriparatide 250 microgram/mL injection, 2.4 mL cartridge**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15152L | 1 | 5 | 0.00 | 173.14 | 25.00 | [a] Ritosa [XT] |

## ANTI-PARATHYROID AGENTS

### *Calcitonin preparations*

### CALCITONIN SALMON

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***16678***

Symptomatic Paget disease of bone

**Clinical criteria:**

- The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**Authority Required**

***16575***

Hypercalcaemia

**Clinical criteria:**

- The treatment must be initiated in a hospital, **AND**
- The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**calcitonin salmon 100 units/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2997R NP | 3 | 5 | 0.00 | *125.70 | 25.00 | Miacalcic 100 [EU] |

### *Other anti-parathyroid agents*

### CINACALCET

**Authority Required (STREAMLINED)**

***10068***

Secondary hyperparathyroidism

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**
- Patient must have achieved a decrease of at least 30% in intact parathyroid hormone (iPTH) concentrations after 6 months treatment; **OR**
- Patient must have an intact parathyroid (iPTH) concentration greater than 15 pmol/L and an (adjusted) serum calcium concentration of less than 2.6 mmol/L after 6 months.

During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

**cinacalcet 30 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9157Y NP | 1 | 5 | 0.00 | 30.69 | 25.00 | [a] Cinacalcet Viatris [AL] | [a] Pharmacor Cinacalcet [CR] |

**cinacalcet 60 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9158B NP | 1 | 5 | 0.00 | 47.04 | 25.00 | [a] Cinacalcet Viatris [AL] | [a] Pharmacor Cinacalcet [CR] |

**cinacalcet 90 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9159C NP | 1 | 5 | 0.00 | 63.37 | 25.00 | [a] Cinacalcet Viatris [AL] | [a] Pharmacor Cinacalcet [CR] |

# ANTIINFECTIVES FOR SYSTEMIC USE

## ANTIBACTERIALS FOR SYSTEMIC USE

### TETRACYCLINES

#### *Tetracyclines*

### DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**doxycycline 100 mg modified release capsule, 7**

| 2708M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | [B]1.43 | 18.53 | 18.64 | [a] Mayne Pharma Doxycycline [YT] | |
| | | | [B]2.75 | 19.85 | 18.64 | [a] Doryx [YN] | |

**doxycycline 100 mg modified release capsule, 7**

| 3322W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | [B]1.43 | 18.53 | 18.64 | [a] Mayne Pharma Doxycycline [YT] | |
| | | | [B]2.75 | 19.85 | 18.64 | [a] Doryx [YN] | |

**doxycycline 100 mg tablet, 7**

| 2709N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 17.10 | 18.64 | [a] APX-Doxycycline [TX] | [a] Doxsig [RW] |
| | | | | | | [a] DOXYCYCLINE-WGR [WG] | [a] Doxylin 100 [AF] |

**doxycycline 100 mg tablet, 7**

| 3321T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APX-Doxycycline [TX] | [a] Doxsig [RW] |
| | | | | | | [a] DOXYCYCLINE-WGR [WG] | [a] Doxylin 100 [AF] |

**doxycycline 100 mg tablet, 7**

| 5082L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Blooms The Chemist Doxycycline [BG] | [a] Doxycycline Sandoz [HX] |

**doxycycline 100 mg tablet, 7**

| 9105F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 17.10 | 18.64 | [a] Blooms The Chemist Doxycycline [BG] | [a] Doxycycline Sandoz [HX] |

### DOXYCYCLINE

**Restricted benefit**

***4514***

Pelvic inflammatory disease

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**doxycycline 100 mg tablet, 7**

| 2702F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 0 | 0.00 | *25.32 | 25.00 | [a] APX-Doxycycline [TX] | [a] Doxsig [RW] |
| | | | | | | [a] DOXYCYCLINE-WGR [WG] | [a] Doxylin 100 [AF] |

**doxycycline 100 mg tablet, 7**

| 9107H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 0 | 0.00 | *25.32 | 25.00 | [a] Blooms The Chemist Doxycycline [BG] | [a] Doxycycline Sandoz [HX] |

**doxycycline 100 mg modified release capsule, 7**

| 2703G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 0 | [B]5.72 | *31.04 | 25.00 | [a] Mayne Pharma Doxycycline [YT] | |
| | | | [B]11.00 | *36.32 | 25.00 | [a] Doryx [YN] | |

## DOXYCYCLINE

**Restricted benefit**

***4485***

Urethritis

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

### doxycycline 100 mg tablet, 7

| 2714W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 0 | 0.00 | *22.59 | 24.13 | [a] APX-Doxycycline [TX] | [a] Doxsig [RW] |
| | | | | | | [a] DOXYCYCLINE-WGR [WG] | [a] Doxylin 100 [AF] |

### doxycycline 100 mg tablet, 7

| 9108J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 0 | 0.00 | *22.59 | 24.13 | [a] Blooms The Chemist Doxycycline [BG] | [a] Doxycycline Sandoz [HX] |

### doxycycline 100 mg modified release capsule, 21

| 2715X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 3.12 | 25.30 | 23.72 | [a] Mayne Pharma Doxycycline [YT] |

### doxycycline 100 mg tablet, 21

| 10176N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 22.18 | 23.72 | [a] APX-Doxycycline [TX] | [a] Doxsig [RW] |
| | | | | | | [a] Doxylin 100 [AF] | |

## DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

***6200***

Severe acne

### doxycycline 100 mg modified release capsule, 7

| 10777F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | [B]5.72 | *31.04 | 25.00 | [a] Mayne Pharma Doxycycline [YT] | |
| | | | [B]11.00 | *36.32 | 25.00 | [a] Doryx [YN] | |

### doxycycline 100 mg tablet, 7

| 10779H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *25.32 | 25.00 | [a] APX-Doxycycline [TX] | [a] Doxsig [RW] |
| | | | | | | [a] DOXYCYCLINE-WGR [WG] | [a] Doxylin 100 [AF] |

### doxycycline 100 mg tablet, 7

| 10781K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *25.32 | 25.00 | [a] Blooms The Chemist Doxycycline [BG] | [a] Doxycycline Sandoz [HX] |

## DOXYCYCLINE

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

***15625***

Severe acne

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### doxycycline 100 mg modified release capsule, 7

| 14443E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 2 | [B]11.44 | *47.72 | 25.00 | [a] Mayne Pharma Doxycycline [YT] | |
| | | | [B]22.00 | *58.28 | 25.00 | [a] Doryx [YN] | |

**doxycycline 100 mg tablet, 7**

| 14480D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 2 | 0.00 | *36.28 | 25.00 | [a] APX-Doxycycline [TX] | [a] Doxsig [RW] |
| | | | | | | [a] DOXYCYCLINE-WGR [WG] | [a] Doxylin 100 [AF] |

**doxycycline 100 mg tablet, 7**

| 14511R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 2 | 0.00 | *36.28 | 25.00 | [a] Blooms The Chemist Doxycycline [BG] | [a] Doxycycline Sandoz [HX] |

## DOXYCYCLINE

**Restricted benefit**

***4539***

Bronchiectasis

**Population criteria:**

- Patient must be aged 8 years or older.

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hyclate (hydrochloride)), doxycycline tablet 50 mg (as monohydrate) and doxycycline modified release capsule 50 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

***4475***

Chronic bronchitis

**Population criteria:**

- Patient must be aged 8 years or older.

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hyclate (hydrochloride)), doxycycline tablet 50 mg (as monohydrate) and doxycycline modified release capsule 50 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

***4529***

Severe acne

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hyclate (hydrochloride)), doxycycline tablet 50 mg (as monohydrate) and doxycycline modified release capsule 50 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**doxycycline 50 mg modified release capsule, 25**

| 2707L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | [B]2.41 | 19.68 | 18.81 | [a] Mayne Pharma Doxycycline [YT] | |
| | | | [B]4.74 | 22.01 | 18.81 | [a] Doryx [YN] | |

**doxycycline 50 mg tablet, 25**

| 2711Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.27 | 18.81 | [a] APX-Doxycycline [TX] | [a] Doxsig [RW] |
| | | | | | | [a] DOXYCYCLINE-WGR [WG] | [a] Doxylin 50 [AF] |

**doxycycline 50 mg tablet, 25**

| 9106G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.27 | 18.81 | [a] Doxycycline Sandoz [HX] |

## DOXYCYCLINE

**Restricted benefit**

***15596***

Bronchiectasis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 8 years or older.

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hyclate (hydrochloride)), doxycycline tablet 50 mg (as monohydrate) and doxycycline modified release capsule 50 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

***15659***

Chronic bronchitis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 8 years or older.

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hyclate (hydrochloride)), doxycycline tablet 50 mg (as monohydrate) and doxycycline modified release capsule 50 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**

***15686***

Severe acne

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Note** Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hyclate (hydrochloride)), doxycycline tablet 50 mg (as monohydrate) and doxycycline modified release capsule 50 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

### doxycycline 50 mg tablet, 25

| 14307B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *20.18 | 21.72 | [a] APX-Doxycycline [TX] | [a] Doxsig [RW] |
| | | | | | | [a] DOXYCYCLINE-WGR [WG] | [a] Doxylin 50 [AF] |

### doxycycline 50 mg tablet, 25

| 14513W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *20.18 | 21.72 | [a] Doxycycline Sandoz [HX] |

### doxycycline 50 mg modified release capsule, 25

| 14484H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | [B]4.82 | *25.00 | 21.72 | [a] Mayne Pharma Doxycycline [YT] | |
| | | | [B]9.48 | *29.66 | 21.72 | [a] Doryx [YN] | |

## MINOCYCLINE

**Caution** There are concerns about the incidence of benign intracranial hypertension associated with this drug.

**Restricted benefit**

***5995***

Severe acne

**Clinical criteria:**

- The condition must not be responding to other tetracyclines.

**Caution** There are concerns about the incidence of benign intracranial hypertension associated with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### minocycline 50 mg tablet, 60

| 1616C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 26.77 | 25.00 | [a] Akamin 50 [AF] | [a] Minomycin-50 [AS] |

## MINOCYCLINE

**Caution** There are concerns about the incidence of benign intracranial hypertension associated with this drug.

**Restricted benefit**

***15657***

Severe acne

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be responding to other tetracyclines.

**Caution** There are concerns about the incidence of benign intracranial hypertension associated with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### minocycline 50 mg tablet, 60

| 14483G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *39.18 | 25.00 | [a] Akamin 50 [AF] | [a] Minomycin-50 [AS] |

## BETA-LACTAM ANTIBACTERIALS, PENICILLINS

## *Penicillins with extended spectrum*

### AMOXICILLIN

**amoxicillin 100 mg/mL powder for oral liquid, 20 mL**

| 1888J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | ‡1 | 1 | 0.00 | 24.25 | 25.00 | Amoxil [AS] |

**amoxicillin 100 mg/mL powder for oral liquid, 20 mL**

| 3310F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 24.25 | 25.00 | Amoxil [AS] |

**amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL**

| 1886G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | ‡1 | 1 | 0.00 | 20.35 | 22.34 | [a] AMOXICILLIN MEDSURGE [DZ] | [a] Amoxycillin Sandoz [SZ] |
| | | | | | | [a] APO-Amoxycillin [TX] | |
| | | | [B]4.50 | 24.85 | 22.34 | [a] Amoxil [AS] | |

**amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL**

| 3302T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 20.35 | 22.34 | [a] AMOXICILLIN MEDSURGE [DZ] | [a] Amoxycillin Sandoz [SZ] |
| | | | | | | [a] APO-Amoxycillin [TX] | |
| | | | [B]4.50 | 24.85 | 22.34 | [a] Amoxil [AS] | |

**amoxicillin 250 mg capsule, 20**

| 3301R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Alphamox 250 [AF] | [a] AMILOXYN [RF] |
| | | | | | | [a] APO-Amoxycillin [TX] | [a] Cilamox [AL] |

**amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL**

| 1887H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | ‡1 | 1 | 0.00 | 20.35 | 22.34 | [a] AMOXICILLIN MEDSURGE [DZ] | [a] AMOXICILLIN-WGR [WG] |
| | | | | | | [a] Amoxycillin Sandoz [SZ] | [a] APO-Amoxycillin [TX] |
| | | | [B]4.27 | 24.62 | 22.34 | [a] Amoxil Forte [AS] | |

**amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL**

| 3393N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 20.35 | 22.34 | [a] AMOXICILLIN MEDSURGE [DZ] | [a] AMOXICILLIN-WGR [WG] |
| | | | | | | [a] Amoxycillin Sandoz [SZ] | [a] APO-Amoxycillin [TX] |
| | | | [B]4.27 | 24.62 | 22.34 | [a] Amoxil Forte [AS] | |

**amoxicillin 500 mg capsule, 20**

| 3300Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Alphamox 500 [AF] | [a] AMILOXYN [RF] |
| | | | | | | [a] AMOXICILLIN-WGR [WG] | [a] Amoxycillin generichealth 500 [GQ] |
| | | | | | | [a] Amoxycillin Sandoz [SZ] | [a] APO-Amoxycillin [TX] |
| | | | | | | [a] Blooms The Chemist Amoxicillin [BG] | [a] Cilamox [AL] |
| | | | [B]4.41 | 21.51 | 18.64 | [a] Amoxil [AS] | |

**amoxicillin 500 mg/5 mL powder for oral liquid, 100 mL**

| 5225B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 20.62 | 22.61 | Maxamox [SZ] |

**amoxicillin 500 mg/5 mL powder for oral liquid, 100 mL**

| 8705E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | ‡1 | 1 | 0.00 | 20.62 | 22.61 | Maxamox [SZ] |

### AMOXICILLIN

**Restricted benefit**

***5843***

Chronic bronchitis

**Clinical criteria:**

- Patient must have acute exacerbations of the condition.

**amoxicillin 1 g tablet, 14**

| 8581P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 17.10 | 18.64 | [a] Amoxycillin Sandoz [BG] | |
| | | | [B]1.00 | 18.10 | 18.64 | [a] Maxamox [SZ] | |

## AMOXICILLIN

**Authority Required**

***5863***

Infection suspected or proven to be due to a susceptible organism

**Clinical criteria:**

- The treatment must be for patients who require a liquid formulation and in whom the syrup formulations are unsuitable.

**amoxicillin 100 mg/mL powder for oral liquid, 20 mL**

| 9714G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | ‡1 | 1 | 0.00 | 24.25 | 25.00 | Amoxil [AS] |

## AMOXICILLIN

**Authority Required (STREAMLINED)**

***10402***

Infection

**Clinical criteria:**

- Patient must be a male with acute cystitis; **OR**
- Patient must have pyelonephritis; **OR**
- Patient must have a tooth avulsion; **OR**
- Patient must have salmonella enteritis; **OR**
- Patient must have community acquired pneumonia; **OR**
- Patient must have a condition requiring prolonged oral antibiotic therapy.

**amoxicillin 500 mg capsule, 20**

| 11947T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *19.84 | 21.38 | [a] Alphamox 500 [AF] | [a] AMILOXYN [RF] |
| | | | | | | [a] AMOXICILLIN-WGR [WG] | [a] Amoxycillin generichealth 500 [GQ] |
| | | | | | | [a] Amoxycillin Sandoz [SZ] | [a] APO-Amoxycillin [TX] |
| | | | | | | [a] Blooms The Chemist Amoxicillin [BG] | [a] Cilamox [AL] |
| | | | [B]8.82 | 28.66 | 21.38 | [a] Amoxil [AS] | |

## AMOXICILLIN

**Authority Required (STREAMLINED)**

***10404***

Infection

**Clinical criteria:**

- Patient must have a condition requiring prolonged oral antibiotic therapy.

**amoxicillin 250 mg capsule, 20**

| 11998L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *19.84 | 21.38 | [a] Alphamox 250 [AF] | [a] AMILOXYN [RF] |
| | | | | | | [a] APO-Amoxycillin [TX] | [a] Cilamox [AL] |

## AMOXICILLIN

**Authority Required (STREAMLINED)**

***10416***

Community acquired pneumonia

**Clinical criteria:**

- Patient must have community acquired pneumonia.

**amoxicillin 1 g tablet, 14**

| 12002Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 17.10 | 18.64 | [a] Amoxycillin Sandoz [BG] | |
| | | | [B]1.00 | 18.10 | 18.64 | [a] Maxamox [SZ] | |

## AMOXICILLIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**amoxicillin 250 mg capsule, 20**

| 1884E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Alphamox 250 [AF] | [a] AMILOXYN [RF] |
| | | | | | | [a] APO-Amoxycillin [TX] | [a] Cilamox [AL] |

**amoxicillin 500 mg capsule, 20**

| 1889K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Alphamox 500 [AF] | [a] AMILOXYN [RF] |
| | | | | | | [a] AMOXICILLIN-WGR [WG] | [a] Amoxycillin generichealth 500 [GQ] |
| | | | | | | [a] Amoxycillin Sandoz [SZ] | [a] APO-Amoxycillin [TX] |
| | | | | | | [a] Blooms The Chemist Amoxicillin [BG] | [a] Cilamox [AL] |
| | | | [B]4.41 | 21.51 | 18.64 | [a] Amoxil [AS] | |

## *Beta-lactamase sensitive penicillins*

### BENZATHINE BENZYLPENICILLIN

**benzathine benzylpenicillin tetrahydrate 600 000 units (517 mg)/1.17 mL injection, 10 x 1.17 mL syringes**

| 11723B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 211.54 | 25.00 | Bicillin L-A [PF] |

**benzathine benzylpenicillin tetrahydrate 600 000 units (517 mg)/1.17 mL injection, 10 x 1.17 mL syringes**

| 11735P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 211.54 | 25.00 | Bicillin L-A [PF] |

### BENZATHINE BENZYLPENICILLIN

**Note** Pharmaceutical benefits that have the brand Lentocilin S 1200 (Portugal), or the brand Benzylpenicillin benzathine (Brancaster Pharma, UK), or the brand Benzetacil (Spain) may be substituted for pharmaceutical benefits that have the brand Bicillin L-A in case of shortage.

**benzathine benzylpenicillin 1.2 million units powder for injection, 1 vial**

| 15365Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 10 | 0 | 0.00 | *490.44 | 25.00 | [a] Benzylpenicillin benzathine (Brancaster Pharma, UK) [QY] |

**benzathine benzylpenicillin 1.2 million units powder for injection, 1 vial**

| 15389Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 10 | 0 | 0.00 | *490.44 | 25.00 | [a] Benzylpenicillin benzathine (Brancaster Pharma, UK) [QY] |

**benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [4 mL ampoule], 1 pack**

| 15058M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 10 | 0 | 0.00 | *490.44 | 25.00 | [a] Lentocilin S 1200 (Portugal) [NG] |

**benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [4 mL ampoule], 1 pack**

| 15063T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 10 | 0 | 0.00 | *490.44 | 25.00 | [a] Lentocilin S 1200 (Portugal) [NG] |

**benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [4 mL ampoule], 1 pack**

| 15506D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 10 | 0 | 0.00 | *767.24 | 25.00 | [a] Benzetacil (Spain) [KQ] |

**benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [4 mL ampoule], 1 pack**

| 15527F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 10 | 0 | 0.00 | *767.24 | 25.00 | [a] Benzetacil (Spain) [KQ] |

**benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes**

| 2267H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 327.06 | 25.00 | [a] Bicillin L-A [PF] |

**benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes**

| 5027N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 327.06 | 25.00 | [a] Bicillin L-A [PF] |

## BENZYLPENICILLIN

**benzylpenicillin 600 mg injection, 1 vial**

| 1775K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 10 | 1 | 0.00 | *71.94 | 25.00 | [a] BenPen [SZ] | [a] PEN G Sandoz [HX] |

**benzylpenicillin 600 mg injection, 1 vial**

| 3398W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 10 | 0 | 0.00 | *71.94 | 25.00 | [a] BenPen [SZ] | [a] PEN G Sandoz [HX] |

**benzylpenicillin 3 g injection, 1 vial**

| 3399X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 10 | 0 | 0.00 | *107.24 | 25.00 | BenPen [SZ] |

## BENZYLPENICILLIN

**Caution** If prescribed for sepsis (or suspected sepsis) by an authorised PBS prescriber who is not a medical practitioner, the decision to prescribe this benefit is to be shared with a medical practitioner.

**benzylpenicillin 3 g injection, 1 vial**

| 2647H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 10 | 0 | 0.00 | *107.24 | 25.00 | BenPen [SZ] |

## PHENOXYMETHYLPENICILLIN

**phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL**

| 5024K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | 0 | 0.00 | *27.15 | 25.00 | Phenoxymethylpenicillin-AFT [AE] |

**phenoxymethylpenicillin 125 mg/5 mL powder for oral liquid, 100 mL**

| 8976K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *27.15 | 25.00 | Phenoxymethylpenicillin-AFT [AE] |

**phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL**

| 5012T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | 0 | 0.00 | *25.72 | 25.00 | Cilicaine V [AF] |

**phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL**

| 9143F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *25.72 | 25.00 | Cilicaine V [AF] |

**phenoxymethylpenicillin 250 mg tablet, 25**

| 1787C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *22.50 | 24.04 | Aspecillin VK [AF] |

**phenoxymethylpenicillin 250 mg tablet, 25**

| 3360W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | 0 | 0.00 | *22.50 | 24.04 | Aspecillin VK [AF] |

**phenoxymethylpenicillin 250 mg capsule, 50**

| 1789E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 18.43 | 19.97 | Cilicaine VK [AF] | LPV [IL] |

**phenoxymethylpenicillin 250 mg capsule, 50**

| 3363B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 18.43 | 19.97 | Cilicaine VK [AF] | LPV [IL] |

**phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5029Q DP | 2 | 0 | 0.00 | *28.95 | 25.00 | Phenoxymethylpenicillin-AFT [AE] |

**phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8977L NP | 2 | 1 | 0.00 | *28.95 | 25.00 | Phenoxymethylpenicillin-AFT [AE] |

**phenoxymethylpenicillin 500 mg capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2965C NP | 1 | 0 | 0.00 | 19.65 | 21.19 | Cilicaine VK [AF] | LPV [IL] |

**phenoxymethylpenicillin 500 mg capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3364C DP | 1 | 0 | 0.00 | 19.65 | 21.19 | Cilicaine VK [AF] | LPV [IL] |

**phenoxymethylpenicillin 500 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3028J NP | 2 | 0 | 0.00 | *24.94 | 25.00 | Aspecillin VK [AF] |

**phenoxymethylpenicillin 500 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3361X DP | 2 | 0 | 0.00 | *24.94 | 25.00 | Aspecillin VK [AF] |

## PHENOXYMETHYLPENICILLIN

**Restricted benefit**

***5697***

Recurrent streptococcal infections (including rheumatic fever)

**Clinical criteria:**

- The treatment must be for prophylaxis.

**phenoxymethylpenicillin 250 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1703P NP | 2 | 5 | 0.00 | *22.50 | 24.04 | Aspecillin VK [AF] |

**phenoxymethylpenicillin 250 mg capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1705R NP | 1 | 5 | 0.00 | 18.43 | 19.97 | Cilicaine VK [AF] | LPV [IL] |

## PHENOXYMETHYLPENICILLIN

**Restricted benefit**

***14947***

Recurrent streptococcal infections (including rheumatic fever)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for prophylaxis.

**phenoxymethylpenicillin 250 mg capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13968E NP | 2 | 5 | 0.00 | *22.50 | 24.04 | Cilicaine VK [AF] | LPV [IL] |

**phenoxymethylpenicillin 250 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14044E NP | 4 | 5 | 0.00 | *30.64 | 25.00 | Aspecillin VK [AF] |

### *Beta-lactamase resistant penicillins*

## DICLOXACILLIN

**Restricted benefit**

***5268***

Serious staphylococcal infection

**dicloxacillin 250 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5096F DP | 1 | 0 | 0.00 | 18.90 | 20.44 | [a] ARX-Dicloxacillin [XT] | [a] DICLOXACILLIN VIATRIS 250 [MQ] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5096F | | | [B]1.83 | 20.73 | 20.44 | [a] Distaph 250 [AF] | |

**dicloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5097G DP | 1 | 0 | 0.00 | 22.21 | 23.75 | [a] ARX-Dicloxacillin [XT] | [a] DICLOXACILLIN VIATRIS 500 [MQ] |
| | | | [B]1.90 | 24.11 | 23.75 | [a] Distaph 500 [AF] | |

## DICLOXACILLIN

**Restricted benefit**

***5415***

Serious staphylococcal infection

**dicloxacillin 250 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8121K NP MW | 1 | 0 | 0.00 | 18.90 | 20.44 | [a] ARX-Dicloxacillin [XT] | [a] DICLOXACILLIN VIATRIS 250 [MQ] |
| | | | [B]1.83 | 20.73 | 20.44 | [a] Distaph 250 [AF] | |

**dicloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8122L NP MW | 1 | 0 | 0.00 | 22.21 | 23.75 | [a] ARX-Dicloxacillin [XT] | [a] DICLOXACILLIN VIATRIS 500 [MQ] |
| | | | [B]1.90 | 24.11 | 23.75 | [a] Distaph 500 [AF] | |

## DICLOXACILLIN

**Authority Required (STREAMLINED)**

***6188***

Osteomyelitis

**dicloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10790X | 2 | 1 | 0.00 | *30.06 | 25.00 | [a] ARX-Dicloxacillin [XT] | [a] DICLOXACILLIN VIATRIS 500 [MQ] |
| | | | [B]3.80 | *33.86 | 25.00 | [a] Distaph 500 [AF] | |

## FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

***5414***

Serious staphylococcal infection

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**flucloxacillin 250 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1526H NP MW | 1 | 0 | 0.00 | 18.46 | 20.00 | [a] Flopen [AL] | [a] Flopen Viatris [MQ] |
| | | | | | | [a] Staphylex 250 [AF] | |

**flucloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1527J NP MW | 1 | 0 | 0.00 | 22.79 | 24.33 | [a] Flopen [AL] | [a] Flopen Viatris [MQ] |
| | | | | | | [a] Staphylex 500 [AF] | |

## FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

***5298***

Serious staphylococcal infection

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5257Q DP | ‡1 | 0 | 0.00 | 27.88 | 25.00 | Flucil [LN] |

**flucloxacillin 250 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5090X | | | | | | | |
| DP | 1 | 0 | 0.00 | 18.46 | 20.00 | [a] Flopen [AL] | [a] Flopen Viatris [MQ] |
| | | | | | | [a] Staphylex 250 [AF] | |

**flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5258R | | | | | | |
| DP | ‡1 | 0 | 0.00 | 29.19 | 25.00 | Flucil [LN] |

**flucloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5091Y | | | | | | | |
| DP | 1 | 0 | 0.00 | 22.79 | 24.33 | [a] Flopen [AL] | [a] Flopen Viatris [MQ] |
| | | | | | | [a] Staphylex 500 [AF] | |

## FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**

***5297***

Serious staphylococcal infection

**flucloxacillin 125 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9149M | | | | | | |
| NP MW | ‡1 | 1 | 0.00 | 27.88 | 25.00 | Flucil [LN] |

**flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9150N | | | | | | |
| NP MW | ‡1 | 1 | 0.00 | 29.19 | 25.00 | Flucil [LN] |

## FLUCLOXACILLIN

**Caution** Severe cholestatic jaundice has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Authority Required (STREAMLINED)**

***17381***

Osteomyelitis

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where this prescription is to continue existing therapy with this medicine.

**flucloxacillin 500 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10788T | | | | | | | |
| NP | 2 | 1 | 0.00 | *31.22 | 25.00 | [a] Flopen [AL] | [a] Flopen Viatris [MQ] |
| | | | | | | [a] Staphylex 500 [AF] | |

### *Combinations of penicillins, incl. beta-lactamase inhibitors*

## AMOXICILLIN + CLAVULANIC ACID

**Authority Required (STREAMLINED)**

***10413***

Infection

**Clinical criteria:**

- Patient must have periorbital (preseptal) cellulitis; **OR**
- Patient must have postpartum endometritis; **OR**
- Patient must have an exacerbation of bronchiectasis; **OR**
- Patient must have pyelonephritis; **OR**
- Patient must have pneumonia acquired in hospital or aged care; **OR**
- Patient must have a diabetic foot infection; **OR**
- Patient must have a condition requiring prolonged oral antibiotic therapy.

**amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11933C | | | | | | | |
| NP MW | 2 | 0 | 0.00 | *21.00 | 22.54 | [a] Alphaclav Duo Forte Viatris [AL] | [a] AMCLAVOX DUO FORTE 875/125 [RW] |
| | | | | | | [a] AMOXICILLIN/CLAVULANIC ACID-WGR 875/125 [WG] | [a] AmoxyClav generichealth 875/125 [HQ] |

| 11933C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] APO-Amoxycillin and Clavulanic Acid [TX] | [a] APO-AMOXY/CLAV 875/125 [TW] |
| | | | | | | [a] APX-Amoxicillin/Clavulanic Acid [XT] | [a] Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125 [BG] |
| | | | | | | [a] COMOX [DZ] | [a] Curam Duo Forte 875/125 [SZ] |
| | | | [B]12.92 | 33.92 | 22.54 | [a] Augmentin Duo forte [AS] | |

## AMOXICILLIN + CLAVULANIC ACID

**Authority Required (STREAMLINED)**

***10405***

Infection

**Clinical criteria:**

- Patient must be a male with acute cystitis; **OR**
- Patient must have a condition requiring prolonged oral antibiotic therapy.

### amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10

| 11941L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 2 | 0 | 0.00 | *20.44 | 21.98 | [a] Alphaclav Duo Viatris [AL] | [a] AMCLAVOX DUO 500/125 [RW] |
| | | | | | | [a] AMOXICILLIN/CLAVULANIC ACID-WGR 500/125 [WG] | [a] APO-Amoxycillin/ Clavulanic Acid 500/125 [TX] |
| | | | | | | [a] APO-AMOXY/CLAV 500/125 [TW] | [a] APX-Amoxicillin/Clavulanic Acid [XT] |
| | | | | | | [a] COMOX [DZ] | [a] Curam Duo 500/125 [SZ] |
| | | | [B]10.26 | 30.70 | 21.98 | [a] Augmentin Duo [AS] | |

## AMOXICILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.

**Restricted benefit**

***5833***

Infection where resistance to amoxicillin is suspected

**Caution** Hepatotoxicity has been reported with this drug.

**Restricted benefit**

***5894***

Infections where resistance to amoxicillin is proven

**Caution** Hepatotoxicity has been reported with this drug.

### amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL

| 5009P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 20.35 | 22.34 | Curam [SZ] |

### amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL

| 5011R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 20.35 | 22.34 | [a] Curam Duo [SZ] | |
| | | | [B]5.19 | 25.54 | 22.34 | [a] Augmentin Duo 400 [AS] | |

### amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10

| 5008N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.40 | 18.94 | [a] Alphaclav Duo Viatris [AL] | [a] AMCLAVOX DUO 500/125 [RW] |
| | | | | | | [a] AMOXICILLIN/CLAVULANIC ACID-WGR 500/125 [WG] | [a] APO-Amoxycillin/ Clavulanic Acid 500/125 [TX] |
| | | | | | | [a] APO-AMOXY/CLAV 500/125 [TW] | [a] APX-Amoxicillin/Clavulanic Acid [XT] |
| | | | | | | [a] COMOX [DZ] | [a] Curam Duo 500/125 [SZ] |
| | | | [B]5.13 | 22.53 | 18.94 | [a] Augmentin Duo [AS] | |

### amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

| 5006L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.68 | 19.22 | [a] Alphaclav Duo Forte Viatris [AL] | [a] AMCLAVOX DUO FORTE 875/125 [RW] |
| | | | | | | [a] AMOXICILLIN/CLAVULANIC ACID-WGR 875/125 [WG] | [a] AmoxyClav generichealth 875/125 [HQ] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5006L | | | | | | [a] APO-Amoxycillin and Clavulanic Acid [TX] | [a] APO-AMOXY/CLAV 875/125 [TW] |
| | | | | | | [a] APX-Amoxicillin/Clavulanic Acid [XT] | [a] Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125 [BG] |
| | | | | | | [a] COMOX [DZ] | [a] Curam Duo Forte 875/125 [SZ] |
| | | | [B]6.46 | 24.14 | 19.22 | [a] Augmentin Duo forte [AS] | |

## AMOXICILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.

**Restricted benefit**

***5893***

Infection where resistance to amoxicillin is suspected

**Restricted benefit**

***5832***

Infections where resistance to amoxicillin is proven

### amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1892N NP MW | ‡1 | 1 | 0.00 | 20.35 | 22.34 | Curam [SZ] |

### amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8319W NP MW | ‡1 | 1 | 0.00 | 20.35 | 22.34 | [a] Curam Duo [SZ] | |
| | | | [B]5.19 | 25.54 | 22.34 | [a] Augmentin Duo 400 [AS] | |

## AMOXICILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***5893***

Infection where resistance to amoxicillin is suspected

**Caution** Hepatotoxicity has been reported with this drug.

**Restricted benefit**

***5832***

Infections where resistance to amoxicillin is proven

**Caution** Hepatotoxicity has been reported with this drug.

### amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1891M NP MW | 1 | 0 | 0.00 | 17.40 | 18.94 | [a] Alphaclav Duo Viatris [AL] | [a] AMCLAVOX DUO 500/125 [RW] |
| | | | | | | [a] AMOXICILLIN/CLAVULANIC ACID-WGR 500/125 [WG] | [a] APO-Amoxycillin/ Clavulanic Acid 500/125 [TX] |
| | | | | | | [a] APO-AMOXY/CLAV 500/125 [TW] | [a] APX-Amoxicillin/Clavulanic Acid [XT] |
| | | | | | | [a] COMOX [DZ] | [a] Curam Duo 500/125 [SZ] |
| | | | [B]5.13 | 22.53 | 18.94 | [a] Augmentin Duo [AS] | |

## AMOXICILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***5893***

Infection where resistance to amoxicillin is suspected

**Restricted benefit**

***5832***

Infections where resistance to amoxicillin is proven

### amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8254K NP MW | 1 | 0 | 0.00 | 17.68 | 19.22 | [a] Alphaclav Duo Forte Viatris [AL] | [a] AMCLAVOX DUO FORTE 875/125 [RW] |

| 8254K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] AMOXICILLIN/CLAVULANIC ACID-WGR 875/125 [WG] | [a] AmoxyClav generichealth 875/125 [HQ] |
| | | | | | | [a] APO-Amoxycillin and Clavulanic Acid [TX] | [a] APO-AMOXY/CLAV 875/125 [TW] |
| | | | | | | [a] APX-Amoxicillin/Clavulanic Acid [XT] | [a] Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125 [BG] |
| | | | | | | [a] COMOX [DZ] | [a] Curam Duo Forte 875/125 [SZ] |
| | | | [B]6.46 | 24.14 | 19.22 | [a] Augmentin Duo forte [AS] | |

## OTHER BETA-LACTAM ANTIBACTERIALS

### *First-generation cephalosporins*

### CEFALEXIN

**cefalexin 125 mg/5 mL powder for oral liquid, 100 mL**

| 3094W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | ‡1 | 1 | 0.00 | 20.35 | 22.34 | [a] Cefalexin Sandoz [SZ] | [a] Ibilex 125 [AF] |

**cefalexin 125 mg/5 mL powder for oral liquid, 100 mL**

| 3319Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 20.35 | 22.34 | [a] Cefalexin Sandoz [SZ] | [a] Ibilex 125 [AF] |

**cefalexin 250 mg capsule, 20**

| 3317N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Cephalexin [TX] | [a] Cefalexin Viatris [AL] |
| | | | | | | [a] Ibilex 250 [AF] | |
| | | | [B]4.47 | 21.57 | 18.64 | [a] Keflex [AS] | |

**cefalexin 250 mg/5 mL powder for oral liquid, 100 mL**

| 3095X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | ‡1 | 1 | 0.00 | 20.45 | 22.44 | [a] Cefalexin Sandoz [SZ] | [a] Ibilex 250 [AF] |
| | | | [B]5.91 | 26.36 | 22.44 | [a] Keflex [AS] | |

**cefalexin 250 mg/5 mL powder for oral liquid, 100 mL**

| 3320R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 20.45 | 22.44 | [a] Cefalexin Sandoz [SZ] | [a] Ibilex 250 [AF] |
| | | | [B]5.91 | 26.36 | 22.44 | [a] Keflex [AS] | |

**cefalexin 500 mg capsule, 20**

| 3318P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Cephalexin [TX] | [a] Blooms The Chemist Cefalexin [BG] |
| | | | | | | [a] Cefalexin Sandoz [SZ] | [a] Cephalex 500 [CR] |
| | | | | | | [a] Cephalexin generichealth [GQ] | [a] CEPHALEXIN-WGR [WG] |
| | | | | | | [a] Ibilex 500 [AF] | |
| | | | [B]5.98 | 23.08 | 18.64 | [a] Keflex [AS] | |

### CEFALEXIN

**Authority Required (STREAMLINED)**

***4243***

Prophylaxis of urinary tract infection

**cefalexin 250 mg capsule, 20**

| 2655R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *19.84 | 21.38 | [a] APO-Cephalexin [TX] | [a] Cefalexin Viatris [AL] |
| | | | | | | [a] Ibilex 250 [AF] | |
| | | | [B]8.94 | 28.78 | 21.38 | [a] Keflex [AS] | |

### CEFALEXIN

**Authority Required (STREAMLINED)**

***17381***

Osteomyelitis

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where this prescription is to continue existing therapy with this medicine.

**cefalexin 500 mg capsule, 20**

| 10778G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *19.84 | 21.38 | [a] APO-Cephalexin [TX] | [a] Blooms The Chemist Cefalexin [BG] |
| | | | | | | [a] Cefalexin Sandoz [SZ] | [a] Cephalex 500 [CR] |
| | | | | | | [a] Cephalexin generichealth [GQ] | [a] CEPHALEXIN-WGR [WG] |
| | | | | | | [a] Ibilex 500 [AF] | |
| | | | [B]11.96 | 31.80 | 21.38 | [a] Keflex [AS] | |

## CEFALEXIN

**Authority Required (STREAMLINED)**

***10410***

Infection

**Clinical criteria:**

- Patient must have a pin-site infection; **OR**
- Patient must have an infection following cardiac device insertion; **OR**
- Patient must have acute otitis externa; **OR**
- Patient must have streptococcal pharyngitis or tonsillitis; **OR**
- Patient must have mastitis; **OR**
- Patient must have periorbital (preseptal) cellulitis; **OR**
- Patient must have acute rheumatic fever; **OR**
- Patient must have a diabetic foot infection; **OR**
- Patient must have a widespread infection of dermatitis; **OR**
- Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; **OR**
- Patient must have impetigo; **OR**
- Patient must have pyelonephritis; **OR**
- Patient must have a condition requiring prolonged oral antibiotic therapy.

Midwives may prescribe under this item for the treatment of mastitis only.

**cefalexin 500 mg capsule, 20**

| 11934D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 2 | 0 | 0.00 | *19.84 | 21.38 | [a] APO-Cephalexin [TX] | [a] Blooms The Chemist Cefalexin [BG] |
| | | | | | | [a] Cefalexin Sandoz [SZ] | [a] Cephalex 500 [CR] |
| | | | | | | [a] Cephalexin generichealth [GQ] | [a] CEPHALEXIN-WGR [WG] |
| | | | | | | [a] Ibilex 500 [AF] | |
| | | | [B]11.96 | 31.80 | 21.38 | [a] Keflex [AS] | |

## CEFALEXIN

**Authority Required (STREAMLINED)**

***10412***

Infection

**Clinical criteria:**

- Patient must have impaired renal function, **AND**
- Patient must have a pin-site infection; **OR**
- Patient must have an infection following cardiac device insertion; **OR**
- Patient must have acute otitis externa; **OR**
- Patient must have streptococcal pharyngitis or tonsillitis; **OR**
- Patient must have mastitis; **OR**
- Patient must have periorbital (preseptal) cellulitis; **OR**
- Patient must have acute rheumatic fever; **OR**
- Patient must have a diabetic foot infection; **OR**
- Patient must have a widespread infection of dermatitis; **OR**
- Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; **OR**
- Patient must have impetigo; **OR**
- Patient must have pyelonephritis; **OR**
- Patient must have a condition requiring prolonged oral antibiotic therapy.

Midwives may prescribe under this item for the treatment of mastitis only, where the patient has impaired renal function.

**cefalexin 250 mg capsule, 20**

| 11963P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 2 | 0 | 0.00 | *19.84 | 21.38 | [a] APO-Cephalexin [TX] | [a] Cefalexin Viatris [AL] |
| | | | | | | [a] Ibilex 250 [AF] | |
| | | | [B]8.94 | 28.78 | 21.38 | [a] Keflex [AS] | |

## CEFALEXIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**cefalexin 250 mg capsule, 20**

| 3058Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Cephalexin [TX] | [a] Cefalexin Viatris [AL] |
| | | | | | | [a] Ibilex 250 [AF] | |
| | | | [B]4.47 | 21.57 | 18.64 | [a] Keflex [AS] | |

**cefalexin 500 mg capsule, 20**

| 3119E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Cephalexin [TX] | [a] Blooms The Chemist Cefalexin [BG] |
| | | | | | | [a] Cefalexin Sandoz [SZ] | [a] Cephalex 500 [CR] |
| | | | | | | [a] Cephalexin generichealth [GQ] | [a] CEPHALEXIN-WGR [WG] |
| | | | | | | [a] Ibilex 500 [AF] | |
| | | | [B]5.98 | 23.08 | 18.64 | [a] Keflex [AS] | |

## CEFAZOLIN

**Restricted benefit**
***5883***
Cellulitis

**cefazolin 1 g injection, 5 vials**

| 1799Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *22.92 | 24.46 | Cefazolin-AFT [AE] |

## CEFAZOLIN

**Restricted benefit**
***5867***
Cellulitis

**cefazolin 2 g injection, 10 vials**

| 12115P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 46.59 | 25.00 | Cephazolin Viatris [AL] |

## CEFAZOLIN

**Restricted benefit**
***15964***
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**cefazolin 1 g injection, 5 vials**

| 14698N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 2 | 0 | 0.00 | *22.92 | 24.46 | Cefazolin-AFT [AE] |

**cefazolin 2 g injection, 10 vials**

| 14694J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 46.59 | 25.00 | Cephazolin Viatris [AL] |

## CEFAZOLIN

**Restricted benefit**
***16030***
Septicaemia, suspected
**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

***16029***

Septicaemia, proven

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**cefazolin 1 g injection, 5 vials**

| 1797N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *22.92 | 24.46 | Cefazolin-AFT [AE] |

**cefazolin 2 g injection, 10 vials**

| 12118T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 46.59 | 25.00 | Cephazolin Viatris [AL] |

## *Second-generation cephalosporins*

### CEFACLOR

**Caution** Serum sickness-like reactions have been reported with this drug, especially in children.

**cefaclor 125 mg/5 mL powder for oral liquid, 100 mL**

| 2460L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | ‡1 | 1 | 0.00 | 21.35 | 23.34 | [a] Cefaclor SUN [RA] | [a] Keflor [AF] |
| | | | [B]7.67 | 29.02 | 23.34 | [a] Ceclor [AL] | |

**cefaclor 125 mg/5 mL powder for oral liquid, 100 mL**

| 5046N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 21.35 | 23.34 | [a] Cefaclor SUN [RA] | [a] Keflor [AF] |
| | | | [B]7.67 | 29.02 | 23.34 | [a] Ceclor [AL] | |

**cefaclor 250 mg/5 mL powder for oral liquid, 75 mL**

| 2461M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | ‡1 | 1 | 0.00 | 21.35 | 23.34 | [a] Cefaclor SUN [RA] | [a] Keflor [AF] |
| | | | [B]7.67 | 29.02 | 23.34 | [a] Ceclor [AL] | |

**cefaclor 250 mg/5 mL powder for oral liquid, 75 mL**

| 5047P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 21.35 | 23.34 | [a] Cefaclor SUN [RA] | [a] Keflor [AF] |
| | | | [B]7.67 | 29.02 | 23.34 | [a] Ceclor [AL] | |

**cefaclor 375 mg modified release tablet, 10**

| 1169M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 18.10 | 19.64 | [a] Keflor CD [AF] | |
| | | | [B]7.67 | 25.77 | 19.64 | [a] Ceclor CD [AL] | |

**cefaclor 375 mg modified release tablet, 10**

| 5045M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 18.10 | 19.64 | [a] Keflor CD [AF] | |
| | | | [B]7.67 | 25.77 | 19.64 | [a] Ceclor CD [AL] | |

### CEFUROXIME

**cefuroxime 250 mg tablet, 14**

| 5052X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 18.92 | 20.46 | [a] ARX-Cefuroxime [XT] | [a] Pharmacor Cefuroxime [CR] |

**cefuroxime 250 mg tablet, 14**

| 8292K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 18.92 | 20.46 | [a] ARX-Cefuroxime [XT] | [a] Pharmacor Cefuroxime [CR] |

**cefuroxime 250 mg tablet, 20**

| 11227X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 20.80 | 22.34 | [a] ARX-Cefuroxime [XT] | [a] Pharmacor Cefuroxime [CR] |
| | | | [B]3.10 | 23.90 | 22.34 | [a] Zinnat [AS] | |

**cefuroxime 250 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11228Y | | | | | | | |
| DP | 1 | 0 | 0.00 | 20.80 | 22.34 | [a] ARX-Cefuroxime [XT] | [a] Pharmacor Cefuroxime [CR] |
| | | | [B]3.10 | 23.90 | 22.34 | [a] Zinnat [AS] | |

## *Third-generation cephalosporins*

### CEFTRIAXONE

**Restricted benefit**

***5855***

Gonorrhoea

**ceftriaxone 500 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9058R | | | | | | |
| NP MW | 1 | 0 | 0.00 | 17.10 | 18.64 | Ceftriaxone-AFT [AE] |

### CEFTRIAXONE

**Restricted benefit**

***15964***

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**ceftriaxone 500 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14697M | | | | | | |
| NP MW | 5 | 0 | 0.00 | *28.04 | 25.00 | Ceftriaxone-AFT [AE] |

**ceftriaxone 1 g injection, 10 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14700Q | | | | | | |
| NP MW | 0.5 | 0 | 0.00 | *32.88 | 25.00 | Ceftriaxone Viatris [AL] |

### CEFTRIAXONE

**Note** Pharmaceutical benefits that have the form ceftriaxone 2 g injection, 5 vials and pharmaceutical benefits that have the form ceftriaxone 2 g injection, 10 vials are equivalent for the purposes of substitution.

**Restricted benefit**

***15964***

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**ceftriaxone 2 g injection, 5 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14695K | | | | | | |
| NP MW | 1 | 0 | 0.00 | 27.76 | 25.00 | [a] Ceftriaxone Viatris [AL] |

**ceftriaxone 2 g injection, 10 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14699P | | | | | | |
| NP MW | 0.5 | 0 | 0.00 | *33.01 | 25.00 | [a] Ceftriaxone Viatris [AL] |

### CEFTRIAXONE

**Restricted benefit**

***16030***

Septicaemia, suspected

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

***16029***

Septicaemia, proven

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**ceftriaxone 500 mg injection, 1 vial**

| 1783W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 0 | 0.00 | *28.04 | 25.00 | Ceftriaxone-AFT [AE] |

**ceftriaxone 1 g injection, 10 vials**

| 12114N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 0.5 | 0 | 0.00 | *32.88 | 25.00 | Ceftriaxone Viatris [AL] |

## CEFTRIAXONE

**Note** Pharmaceutical benefits that have the form ceftriaxone 2 g injection, 5 vials and pharmaceutical benefits that have the form ceftriaxone 2 g injection, 10 vials are equivalent for the purposes of substitution.

**Restricted benefit**

***16030***

Septicaemia, suspected

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

***16029***

Septicaemia, proven

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**ceftriaxone 2 g injection, 5 vials**

| 11169W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 27.76 | 25.00 | [a] Ceftriaxone Viatris [AL] |

**ceftriaxone 2 g injection, 10 vials**

| 12112L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 0.5 | 0 | 0.00 | *33.01 | 25.00 | [a] Ceftriaxone Viatris [AL] |

# SULFONAMIDES AND TRIMETHOPRIM

## *Trimethoprim and derivatives*

## TRIMETHOPRIM

**trimethoprim 300 mg tablet, 7**

| 2922T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 17.10 | 18.64 | [a] Trimethoprim Viatris [MQ] | [a] TRIMETHOPRIM-WGR [WG] |
| | | | [B]2.57 | 19.67 | 18.64 | [a] Alprim [AF] | |
| | | | [B]3.73 | 20.83 | 18.64 | [a] Triprim [RW] | |

## TRIMETHOPRIM

**Authority Required (STREAMLINED)**

***4243***

Prophylaxis of urinary tract infection

**trimethoprim 300 mg tablet, 7**

| 2666H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *19.84 | 21.38 | [a] Trimethoprim Viatris [MQ] | [a] TRIMETHOPRIM-WGR [WG] |
| | | | [B]5.14 | *24.98 | 21.38 | [a] Alprim [AF] | |
| | | | [B]7.46 | *27.30 | 21.38 | [a] Triprim [RW] | |

## TRIMETHOPRIM

**Restricted benefit**

***6163***

Prostatitis

**trimethoprim 300 mg tablet, 7**

| 10785P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 4 | 0 | 0.00 | *25.32 | 25.00 | [a] Trimethoprim Viatris [MQ] | [a] TRIMETHOPRIM-WGR [WG] |
| | | | [B]10.28 | *35.60 | 25.00 | [a] Alprim [AF] | |
| | | | [B]14.92 | *40.24 | 25.00 | [a] Triprim [RW] | |

### *Combinations of sulfonamides and trimethoprim, incl. derivatives*

## TRIMETHOPRIM + SULFAMETHOXAZOLE

**Caution** There is an increased risk of severe adverse reactions with this combination in the elderly.

**trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL**

| 3103H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 22.41 | 23.95 | Septrin [RW] |

**trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL**

| 3391L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 22.41 | 23.95 | Septrin [RW] |

**trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10**

| 2951H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 17.10 | 18.64 | [a] Bactrim DS [XO] | [a] Resprim Forte [AF] |
| | | | [B]3.91 | 21.01 | 18.64 | [a] Septrin Forte [RW] | |

**trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10**

| 3390K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Bactrim DS [XO] | [a] Resprim Forte [AF] |
| | | | [B]3.91 | 21.01 | 18.64 | [a] Septrin Forte [RW] | |

## TRIMETHOPRIM + SULFAMETHOXAZOLE

**Caution** There is an increased risk of severe adverse reactions with this combination in the elderly.

**Authority Required (STREAMLINED)**

***6201***

Prophylaxis of Pneumocystis jiroveci pneumonia

**trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10**

| 10784N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 2 | 0.00 | *22.59 | 24.13 | [a] Bactrim DS [XO] | [a] Resprim Forte [AF] |
| | | | [B]11.73 | *34.32 | 24.13 | [a] Septrin Forte [RW] | |

# MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

### *Macrolides*

## AZITHROMYCIN

**Note** Authority applications for increased quantities and/or repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 888 333.

**azithromycin 200 mg/5 mL powder for oral liquid, 15 mL**

| 8201P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 29.68 | 25.00 | Zithromax [PF] |

## AZITHROMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**azithromycin 500 mg tablet, 2**

| 8336R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 4 | 0 | 0.00 | *31.24 | 25.00 | [a] APO-Azithromycin [TX] | [a] Azithromycin Sandoz [SZ] |
| | | | | | | [a] Azithromycin Viatris [AL] | [a] AZITHROMYCIN-WGR [WG] |
| | | | | | | [a] ZITHRO [RW] | [a] Zithromax [PF] |

## CLARITHROMYCIN

**clarithromycin 250 mg tablet, 14**

| 8318T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 17.85 | 19.39 | [a] Clarithro 250 [RW] | [a] Clarithromycin Sandoz [SZ] |
| | | | | | | [a] Kalixocin [AF] | |
| | | | [B]3.29 | 21.14 | 19.39 | [a] Klacid [GO] | |

## CLARITHROMYCIN

**Restricted benefit**

***5638***

Bordetella pertussis

**Restricted benefit**
***5663***
Atypical mycobacterial infections

**clarithromycin 250 mg/5 mL powder for oral liquid, 50 mL**

| 9192T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 33.23 | 25.00 | Klacid [GO] |

## ERYTHROMYCIN

**erythromycin 250 mg enteric capsule, 25**

| 1404X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 26.00 | 25.00 | Mayne Pharma Erythromycin [YT] |

**erythromycin 250 mg enteric capsule, 25**

| 3325B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 26.00 | 25.00 | Mayne Pharma Erythromycin [YT] |

## ERYTHROMYCIN

**Authority Required (STREAMLINED)**
***6160***
Severe acne
**Clinical criteria:**

- The condition must be one in which tetracycline therapy is inappropriate.

**erythromycin 250 mg enteric capsule, 25**

| 10780J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *37.64 | 25.00 | Mayne Pharma Erythromycin [YT] |

## ERYTHROMYCIN

**Authority Required (STREAMLINED)**
***15710***
Severe acne
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be one in which tetracycline therapy is inappropriate.

**erythromycin 250 mg enteric capsule, 25**

| 14409J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *60.92 | 25.00 | Mayne Pharma Erythromycin [YT] |

## ERYTHROMYCIN ETHYLSUCCINATE

**erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL**

| 2424N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | ‡1 | 1 | 0.00 | 22.31 | 24.30 | E-Mycin 200 [AF] |

**erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL**

| 3334L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 22.31 | 24.30 | E-Mycin 200 [AF] |

**erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL**

| 2428T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | ‡1 | 1 | 0.00 | 23.53 | 25.00 | E-Mycin 400 [AF] |

**erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL**

| 3337P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 23.53 | 25.00 | E-Mycin 400 [AF] |

## ROXITHROMYCIN

**roxithromycin 150 mg tablet, 10**

| 5260W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.41 | 18.95 | [a] APX-Roxithromycin [TY] | [a] Roxar 150 [RW] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5260W | | | | | | [a] Roxithromycin Sandoz [SZ] | [a] ROXITHROMYCIN-WGR [WG] |

**roxithromycin 300 mg tablet, 5**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5261X DP | 1 | 0 | 0.00 | 17.41 | 18.95 | [a] APX-Roxithromycin [TY] | [a] Roxar 300 [RW] |
| | | | | | | [a] Roxithromycin Sandoz [SZ] | [a] ROXITHROMYCIN-WGR [WG] |

## ROXITHROMYCIN

**Authority Required (STREAMLINED)**

***10404***

Infection

**Clinical criteria:**

- Patient must have a condition requiring prolonged oral antibiotic therapy.

**roxithromycin 150 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12001P NP | 2 | 0 | 0.00 | *20.46 | 22.00 | [a] APX-Roxithromycin [TY] | [a] Roxar 150 [RW] |
| | | | | | | [a] Roxithromycin Sandoz [SZ] | [a] ROXITHROMYCIN-WGR [WG] |

**roxithromycin 300 mg tablet, 5**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11993F NP | 2 | 0 | 0.00 | *20.46 | 22.00 | [a] APX-Roxithromycin [TY] | [a] Roxar 300 [RW] |
| | | | | | | [a] Roxithromycin Sandoz [SZ] | [a] ROXITHROMYCIN-WGR [WG] |

## ROXITHROMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**roxithromycin 150 mg tablet, 10**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1760P NP | 1 | 0 | 0.00 | 17.41 | 18.95 | [a] APX-Roxithromycin [TY] | [a] Roxar 150 [RW] |
| | | | | | | [a] Roxithromycin Sandoz [SZ] | [a] ROXITHROMYCIN-WGR [WG] |

**roxithromycin 300 mg tablet, 5**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8016X NP | 1 | 0 | 0.00 | 17.41 | 18.95 | [a] APX-Roxithromycin [TY] | [a] Roxar 300 [RW] |
| | | | | | | [a] Roxithromycin Sandoz [SZ] | [a] ROXITHROMYCIN-WGR [WG] |

### *Lincosamides*

## CLINDAMYCIN

**Restricted benefit**

***5470***

Gram-positive coccal infections

**Clinical criteria:**

- The condition must not be able to be safely and effectively treated with a penicillin.

**clindamycin 150 mg capsule, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3138E NP MW | 2 | 1 | 0.00 | *22.84 | 24.38 | [a] APO-Clindamycin [TX] | [a] Calindamin [RW] |
| | | | | | | [a] Clindamycin LU [XT] | [a] CLINDAMYCIN-WGR [WG] |
| | | | | | | [a] Clindamyk [AF] | [a] Dalacin C [PF] |

## CLINDAMYCIN

**Restricted benefit**

***5487***

Gram-positive coccal infections

**Clinical criteria:**

- The condition must not be able to be safely and effectively treated with a penicillin.

**clindamycin 150 mg capsule, 24**

| 5057E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 18.60 | 20.14 | [a] APO-Clindamycin [TX] | [a] Calindamin [RW] |
| | | | | | | [a] Clindamycin LU [XT] | [a] CLINDAMYCIN-WGR [WG] |
| | | | | | | [a] Clindamyk [AF] | [a] Dalacin C [PF] |

## LINCOMYCIN

**lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules**

| 11366F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 60.26 | 25.00 | LINCOMYCIN SXP [XN] |

**lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules**

| 11380Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 60.26 | 25.00 | LINCOMYCIN SXP [XN] |

# AMINOGLYCOSIDE ANTIBACTERIALS

## *Other aminoglycosides*

## TOBRAMYCIN

**Restricted benefit**

***5498***

Pseudomonas aeruginosa infection

**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- The treatment must be systemic.

**tobramycin 500 mg/5 mL injection, 10 x 5 mL vials**

| 9480Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 189.16 | 25.00 | Tobra-Day [FF] |

## TOBRAMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17349***

Proven Pseudomonas aeruginosa infection

**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- The treatment must be for management.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

**tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules**

| 5442K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 362.44 | 25.00 | [a] Tobi [GO] | [a] TOBRAMYCIN SUN [RA] |
| | | | | | | [a] TOBRAMYCIN WKT [XT] | |

## TOBRAMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17397***

Proven Pseudomonas aeruginosa infection

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result, **AND**
- Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records.

**Population criteria:**

- Patient must be 6 years of age or older.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

**tobramycin 28 mg powder for inhalation, 224 capsules**

| 10066T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 2,460.87 | 25.00 | TOBI podhaler [GO] |

## TOBRAMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17405***

Proven Pseudomonas aeruginosa infection

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have cystic fibrosis, **AND**
- Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, **AND**
- Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

**Population criteria:**

- Patient must be 6 years of age or older.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

**tobramycin 28 mg powder for inhalation, 224 capsules**

| 10074F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 2,460.87 | 25.00 | TOBI podhaler [GO] |

## TOBRAMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17328***

Proven Pseudomonas aeruginosa infection

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have cystic fibrosis, **AND**
- Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, **AND**
- Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

**Population criteria:**

- Patient must be 6 years of age or older.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

**tobramycin 28 mg powder for inhalation, 224 capsules**

| 13965B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *4,812.38 | 25.00 | TOBI podhaler [GO] |

## TOBRAMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17403***

Proven Pseudomonas aeruginosa infection

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have cystic fibrosis, **AND**
- The treatment must be for management.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.

**tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules**

| 14006E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *715.52 | 25.00 | [a] Tobi [GO]<br>[a] TOBRAMYCIN WKT [XT] | [a] TOBRAMYCIN SUN [RA] |

## TOBRAMYCIN

**Restricted benefit**

***5519***

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

***5446***

Septicaemia, suspected

**Restricted benefit**

***5490***

Septicaemia, proven

**tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5**

| 8872Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *70.26 | 25.00 | Pfizer Australia Pty Ltd [PF] |

**tobramycin 80 mg/2 mL injection, 5 x 2 mL vials**

| 1356J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *40.02 | 25.00 | Tobramycin Viatris [AL] |

# QUINOLONE ANTIBACTERIALS

## *Fluoroquinolones*

## CIPROFLOXACIN

**Authority Required**

***5687***

Respiratory tract infection

**Clinical criteria:**

- The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, **AND**
- Patient must be severely immunocompromised.

**Authority Required**

***5722***

Bacterial gastroenteritis

**Clinical criteria:**

- Patient must be severely immunocompromised.

**Authority Required**

***5688***

Infection

**Clinical criteria:**

- The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; **OR**
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

**Authority Required**

***5614***

Bone or joint infection

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; **OR**
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority Required**

***5689***

Epididymo-orchitis

**Clinical criteria:**

- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; **OR**
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority Required**

***5615***
Prostatitis
**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; **OR**
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority Required**
***5780***
Perichondritis of the pinna
**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; **OR**
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

### ciprofloxacin 500 mg tablet, 14

| 1209P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 18.60 | 20.14 | [a] APO-Ciprofloxacin [TX] | [a] C-Flox 500 [AL] |
| | | | | | | [a] Ciprofloxacin Sandoz [SZ] | [a] CIPROFLOXACIN-WGR [WG] |
| | | | | | | [a] Ciprol 500 [RW] | |

### ciprofloxacin 750 mg tablet, 14

| 1210Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 19.58 | 21.12 | [a] APO-Ciprofloxacin [TX] | [a] C-Flox 750 [AL] |
| | | | | | | [a] Ciprofloxacin Sandoz [SZ] | [a] CIPROFLOXACIN-WGR [WG] |
| | | | | | | [a] Ciprol 750 [RW] | |

## CIPROFLOXACIN

**Authority Required**
***5687***
Respiratory tract infection
**Clinical criteria:**
- The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, **AND**
- Patient must be severely immunocompromised.

**Authority Required**
***5722***
Bacterial gastroenteritis
**Clinical criteria:**
- Patient must be severely immunocompromised.

**Authority Required**
***5688***
Infection
**Clinical criteria:**
- The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; **OR**
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

**Authority Required**
***5614***
Bone or joint infection
**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; **OR**
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority Required**
***5689***
Epididymo-orchitis
**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; **OR**
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority Required**

***5615***
Prostatitis
**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; **OR**
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority Required**
***5780***
Perichondritis of the pinna
**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; **OR**
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority Required**
***5666***
Gonorrhoea

**ciprofloxacin 250 mg tablet, 14**

| 1208N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 18.08 | 19.62 | [a] APO-Ciprofloxacin [TX] | [a] C-Flox 250 [AL] |
| | | | | | | [a] Ciprofloxacin Sandoz [SZ] | [a] CIPROFLOXACIN-WGR [WG] |
| | | | | | | [a] Ciprol 250 [RW] | |

## NORFLOXACIN

**Authority Required**
***5744***
Acute bacterial enterocolitis
**Authority Required**
***5806***
Complicated urinary tract infection

**norfloxacin 400 mg tablet, 14**

| 3010K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 18.10 | 19.64 | [a] APO-Norfloxacin [TX] | [a] Roxin [RW] |

# OTHER ANTIBACTERIALS

## *Glycopeptide antibacterials*

## VANCOMYCIN

**Restricted benefit**
***5717***
Endocarditis
**Clinical criteria:**
- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

**vancomycin 500 mg injection, 1 vial**

| 3130R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 0 | 0.00 | *22.86 | 24.40 | [a] Vancomycin Juno [XT] | [a] VANCOMYCIN MEDSURGE [DZ] |
| | | | | | | [a] Vancomycin Viatris [AL] | |

**vancomycin 1 g injection, 1 vial**

| 2269K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 20.62 | 22.16 | [a] Vancomycin Juno [XT] | [a] VANCOMYCIN MEDSURGE [DZ] |
| | | | | | | [a] Vancomycin Viatris [AL] | |

## VANCOMYCIN

**Restricted benefit**
***5716***
Endophthalmitis

**vancomycin 500 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3131T | 5 | 0 | 0.00 | *35.59 | 25.00 | [a] Vancomycin Juno [XT] | [a] VANCOMYCIN MEDSURGE [DZ] |
| | | | | | | [a] Vancomycin Viatris [AL] | |

**vancomycin 1 g injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2270L | 3 | 0 | 0.00 | *33.15 | 25.00 | [a] Vancomycin Juno [XT] | [a] VANCOMYCIN MEDSURGE [DZ] |
| | | | | | | [a] Vancomycin Viatris [AL] | |

## VANCOMYCIN

**Restricted benefit**

***5801***

Endocarditis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be hypersensitive to penicillin.

**vancomycin 500 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3323X DP | 2 | 0 | 0.00 | *22.86 | 24.40 | [a] Vancomycin Juno [XT] | [a] VANCOMYCIN MEDSURGE [DZ] |
| | | | | | | [a] Vancomycin Viatris [AL] | |

**vancomycin 1 g injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5083M DP | 1 | 0 | 0.00 | 20.62 | 22.16 | [a] Vancomycin Juno [XT] | [a] VANCOMYCIN MEDSURGE [DZ] |
| | | | | | | [a] Vancomycin Viatris [AL] | |

## VANCOMYCIN

**Restricted benefit**

***5769***

Infection

**Clinical criteria:**

- The treatment must be initiated in a hospital, **AND**
- The condition must be one in which vancomycin is an appropriate antibiotic.

**vancomycin 500 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14696L MW | 5 | 0 | 0.00 | *35.59 | 25.00 | [a] Vancomycin Juno [XT] | [a] VANCOMYCIN MEDSURGE [DZ] |
| | | | | | | [a] Vancomycin Viatris [AL] | |

**vancomycin 1 g injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14704X MW | 3 | 0 | 0.00 | *33.15 | 25.00 | [a] Vancomycin Juno [XT] | [a] VANCOMYCIN MEDSURGE [DZ] |
| | | | | | | [a] Vancomycin Viatris [AL] | |

### *Steroid antibacterials*

## FUSIDATE

**Restricted benefit**

***4963***

Serious staphylococcal infections

**Clinical criteria:**

- The treatment must be used in combination with another antibiotic, **AND**
- The condition must be proven to be due to a staphylococcus.

**sodium fusidate 250 mg tablet, 36**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2312Q | 1 | 1 | 0.00 | 99.56 | 25.00 | Fucidin [LO] |

## FUSIDATE

**Authority Required (STREAMLINED)**

***6133***
Osteomyelitis
**Clinical criteria:**

- The condition must be methicillin-resistant staphylococcal aureus (MRSA), **AND**
- The treatment must be used in combination with other anti-staphylococcal antibiotics.

**sodium fusidate 250 mg tablet, 36**

| 10782L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 1 | 0.00 | *188.28 | 25.00 | Fucidin [LO] |

## *Imidazole derivatives*

### METRONIDAZOLE

**metronidazole 200 mg tablet, 21**

| 1636D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 17.10 | 18.64 | [a] Metrogyl 200 [XT] | [a] METRONIDAMED [DZ] |

**metronidazole 200 mg tablet, 21**

| 3339R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Metrogyl 200 [XT] | [a] METRONIDAMED [DZ] |

**metronidazole 200 mg/5 mL oral liquid, 100 mL**

| 1630T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | ‡1 | 0 | 0.00 | 32.56 | 25.00 | Flagyl S [VJ] |

**metronidazole 200 mg/5 mL oral liquid, 100 mL**

| 3341W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 32.56 | 25.00 | Flagyl S [VJ] |

**metronidazole 500 mg suppository, 10**

| 1642K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 41.95 | 25.00 | Flagyl [VJ] |

**metronidazole 500 mg suppository, 10**

| 5157K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 41.95 | 25.00 | Flagyl [VJ] |

### METRONIDAZOLE

**Restricted benefit**
***5702***
Anaerobic infections

**metronidazole 400 mg tablet, 21**

| 1621H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 17.87 | 19.41 | [a] Metrogyl 400 [XT] | [a] METRONIDAMED [DZ] |
| | | | [B]2.49 | 20.36 | 19.41 | [a] Flagyl [VJ] | |

### METRONIDAZOLE

**Restricted benefit**
***5701***
Anaerobic infections

**metronidazole 400 mg tablet, 21**

| 5155H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.87 | 19.41 | [a] Metrogyl 400 [XT] | [a] METRONIDAMED [DZ] |
| | | | [B]2.49 | 20.36 | 19.41 | [a] Flagyl [VJ] | |

## *Nitrofuran derivatives*

### NITROFURANTOIN

**Caution** Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

**nitrofurantoin 50 mg capsule, 30**

| 1692C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 1 | 0.00 | 24.03 | 25.00 | [a] ARX-Nitrofurantoin [XT] | [a] Fudantin [NB] |
| | | | | | | [a] Nitrofurantoin BNM [BZ] | |

**nitrofurantoin 100 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1693D NP MW | 1 | 1 | 0.00 | 27.93 | 25.00 | [a] ARX-Nitrofurantoin [XT]<br>[a] Nitrofurantoin BNM [BZ] | [a] Fudantin [NB] |

### *Other antibacterials*

## METHENAMINE HIPPURATE

**methenamine hippurate 1 g tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3124K NP | 1 | 5 | 0.00 | 32.11 | 25.00 | [a] APOHEALTH Urinary Tract Antibacterial [TX]<br>[a] Hiprex [IL]<br>[a] Uramet [AS] | [a] Chemists' Own Urinary Tract Antibacterial [RW]<br>[a] Uraleev [NB] |

## METHENAMINE HIPPURATE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**methenamine hippurate 1 g tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14005D NP | 2 | 5 | 0.00 | *49.86 | 25.00 | [a] APOHEALTH Urinary Tract Antibacterial [TX]<br>[a] Hiprex [IL]<br>[a] Uramet [AS] | [a] Chemists' Own Urinary Tract Antibacterial [RW]<br>[a] Uraleev [NB] |

# ANTIMYCOTICS FOR SYSTEMIC USE

## ANTIMYCOTICS FOR SYSTEMIC USE

### *Triazole and tetrazole derivatives*

## FLUCONAZOLE

**Note** Not for use in vulvovaginal candida infections.

**Authority Required (STREAMLINED)**

***15984***

Cryptococcal meningitis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***15975***

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***6023***

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Authority Required (STREAMLINED)**

***6030***

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

**Authority Required (STREAMLINED)**

***5989***

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Authority Required (STREAMLINED)**

***16034***

Fungal infection

**Clinical criteria:**

- The condition must be serious or life-threatening.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### fluconazole 50 mg capsule, 28

| 1471K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.51 | 21.05 | [a] Dizole 50 [XT] | [a] Fluconazole Sandoz [SZ] |
| | | | | | | [a] Ozole [RA] | |
| | | | [B]7.41 | 26.92 | 21.05 | [a] Diflucan [PF] | |

### fluconazole 100 mg capsule, 28

| 1472L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 24.32 | 25.00 | [a] Dizole 100 [XT] | [a] Fluconazole Sandoz [SZ] |
| | | | | | | [a] Ozole [RA] | |
| | | | [B]10.44 | 34.76 | 25.00 | [a] Diflucan [PF] | |

### fluconazole 200 mg capsule, 28

| 1475P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 33.78 | 25.00 | [a] APO-Fluconazole [TX] | [a] Dizole 200 [XT] |
| | | | | | | [a] Fluconazole Sandoz [SZ] | [a] FLUCONAZOLE-WGR [WG] |
| | | | | | | [a] Fluzole 200 [RW] | [a] Ozole [RA] |
| | | | [B]15.68 | 49.46 | 25.00 | [a] Diflucan [PF] | |

## FLUCONAZOLE

**Note** Not for use in vulvovaginal candida infections.

**Authority Required (STREAMLINED)**

***16141***

Cryptococcal meningitis

**Clinical criteria:**

- Patient must be unable to take a solid dose form of fluconazole.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***16148***

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***6031***

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority Required (STREAMLINED)**

***6032***

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority Required (STREAMLINED)**

***6046***

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority Required (STREAMLINED)**

***16114***

Fungal infection

**Clinical criteria:**

- The condition must be serious or life-threatening, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### fluconazole 50 mg/5 mL powder for oral liquid, 35 mL

| 5446P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 69.55 | 25.00 | Diflucan [PF] |

## ITRACONAZOLE

**Note** Not for use in vulvovaginal candida infections.

**Note** Not for use in superficial mycoses

**Note** One capsule of itraconazole 50 mg (Lozanoc) is therapeutically equivalent to one 100 mg capsule of conventional itraconazole capsules. The recommended dose for Lozanoc is therefore half the recommended dose for conventional itraconazole capsules. Lozanoc 50 mg capsules and conventional itraconazole 100 mg capsules are not interchangeable.

**Authority Required (STREAMLINED)**

***16119***

Systemic aspergillosis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***15978***

Systemic sporotrichosis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***16035***

Systemic histoplasmosis

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***16099***

Disseminated pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***16101***

Chronic pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***16073***

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***16102***

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### itraconazole 50 mg capsule, 60

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10732W NP | 1 | 5 | 0.00 | 115.83 | 25.00 | Lozanoc [YN] |

### itraconazole 100 mg capsule, 60

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8196J NP | 1 | 5 | 0.00 | 115.83 | 25.00 | [a] Itracap [AF]<br>[a] Itrazo [CR] | [a] ITRANOX [RW] |

## POSACONAZOLE

**Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Authority Required**

***16072***

Invasive aspergillosis

**Clinical criteria:**

- Patient must be unable to tolerate alternative therapy; **OR**
- Patient must have disease refractory to alternative therapy.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required**

***16117***

Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; **OR**
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Treatment of neutropenia should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.

Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

No more than 6 months therapy per episode will be PBS-subsidised

**Authority Required**

***16096***

Fungal infection

**Clinical criteria:**

- The condition must be fusariosis; **OR**
- The condition must be zygomycosis; **OR**
- The condition must be coccidioidomycosis; **OR**
- The condition must be chromoblastomycosis; **OR**
- The condition must be mycetoma, **AND**
- Patient must be unable to tolerate alternative therapy; **OR**
- Patient must have disease refractory to alternative therapy.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**posaconazole 100 mg modified release tablet, 24**

| 10460M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 96.20 | 25.00 | [a] Pharmacor Posaconazole [CR] | [a] Posaconazole ARX [XT] |
| | | | | | | [a] POSACONAZOLE DR.REDDY'S [RZ] | [a] Posaconazole Juno [JU] |
| | | | | | | [a] Posaconazole Sandoz [SZ] | [a] POSACONAZOLE-WGR [WG] |
| | | | | | | [a] POSMED [DZ] | |

## VORICONAZOLE

**Note** For patients with graft versus host disease, acute myeloid leukaemia or myelodysplastic syndrome, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Note** For patients undergoing allogeneic haematopoietic stem cell transplant, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 2 months' treatment may be authorised.

**Authority Required**

***16115***

Prophylaxis of invasive fungal infections including both yeasts and moulds

**Clinical criteria:**

- Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; **OR**
- Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; **OR**
- Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**voriconazole 40 mg/mL powder for oral liquid, 70 mL**

| 10168E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 493.53 | 25.00 | Vfend [PF] |

**voriconazole 50 mg tablet, 56**

| 10173K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 47.80 | 25.00 | [a] Voriconazole Sandoz [SZ] | [a] Vttack [AF] |
| | | | | | | [a] Vzole [RW] | |

**voriconazole 200 mg tablet, 56**

| 10198R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 149.80 | 25.00 | [a] Voriconazole Sandoz [SZ] | [a] Vttack [AF] |
| | | | | | | [a] Vzole [RW] | |

## VORICONAZOLE

**Authority Required**

***16042***

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be immunocompromised.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required**

***16094***

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The condition must be caused by Scedosporium species; **OR**
- The condition must be caused by Fusarium species.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required**

***15979***

Serious Candida infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The condition must be caused by species not susceptible to fluconazole; **OR**
- The condition must be resistant to fluconazole; **OR**
- Patient must be unable to tolerate fluconazole.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required**

***15981***

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**voriconazole 50 mg tablet, 56**

| 9363T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 47.80 | 25.00 | [a] Voriconazole Sandoz [SZ]<br>[a] Vzole [RW] | [a] Vttack [AF] |

**voriconazole 200 mg tablet, 56**

| 9364W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 149.80 | 25.00 | [a] Voriconazole Sandoz [SZ]<br>[a] Vzole [RW] | [a] Vttack [AF] |

## VORICONAZOLE

**Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

**Authority Required**

***16042***

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be immunocompromised.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required**

***16094***

Serious fungal infections
Treatment Phase: Treatment and maintenance therapy
**Clinical criteria:**
- The condition must be caused by Scedosporium species; **OR**
- The condition must be caused by Fusarium species.

**Treatment criteria:**
- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required**
***15979***
Serious Candida infections
Treatment Phase: Treatment and maintenance therapy
**Clinical criteria:**
- The condition must be caused by species not susceptible to fluconazole; **OR**
- The condition must be resistant to fluconazole; **OR**
- Patient must be unable to tolerate fluconazole.

**Treatment criteria:**
- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required**
***15981***
Serious invasive mycosis infections
Treatment Phase: Treatment and maintenance therapy
**Clinical criteria:**
- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

**Treatment criteria:**
- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**voriconazole 40 mg/mL powder for oral liquid, 70 mL**

| 9452L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 493.53 | 25.00 | Vfend [PF] |

# ANTIMYCOBACTERIALS

## DRUGS FOR TREATMENT OF TUBERCULOSIS

### *Antibiotics*

### RIFAMPICIN

**Authority Required**
***16043***
Mycobacterium ulcerans infection (Buruli ulcer)
**Clinical criteria:**
- The treatment must be used in combination with another antibiotic for the treatment of Buruli ulcer.

**Treatment criteria:**
- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**rifampicin 150 mg capsule, 100**

| 12190N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 190.50 | 25.00 | Rimycin 150 [AF] |

**rifampicin 150 mg capsule, 10**

| 12200D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 12 | 0 | 0.00 | *226.68 | 25.00 | Rimycin 150 [AF] |

**rifampicin 300 mg capsule, 10**

| 12189M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 12 | 0 | 0.00 | *108.72 | 25.00 | Rimycin 300 [AF] |

**rifampicin 300 mg capsule, 100**

| 12215X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 93.00 | 25.00 | Rimycin 300 [AF] |

### *Hydrazides*

## ISONIAZID

**Restricted benefit**

***15956***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**isoniazid 100 mg tablet, 100**

| 1554T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 22.38 | 23.92 | Arrow Pharma Pty Ltd [RW] |

## DRUGS FOR TREATMENT OF LEPRA

### *Drugs for treatment of lepra*

## DAPSONE

**Dapsone 50 mg tablet, 100**

| 15168H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 319.77 | 25.00 | DAPSOMED [DZ] |

**dapsone 100 mg tablet, 100**

| 1272Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 390.28 | 25.00 | [a] DAPSOMED [DZ] | [a] Link Medical Products Pty Ltd [LM] |

## DAPSONE

**Note** Pharmaceutical benefits that have the brand Dapsone Tablets, USP 25 mg (Rising Pharmaceuticals, USA) may be substituted for pharmaceutical benefits that have the brand Link Medical Products Pty Ltd in case of shortage.

**dapsone 25 mg tablet, 100**

| 8801F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 319.77 | 25.00 | [a] Link Medical Products Pty Ltd [LM] |

**dapsone 25 mg tablet, 100**

| 15517Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 297.93 | 25.00 | [a] Dapsone Tablets, USP 25 mg (Rising Pharmaceuticals, USA) [LM] |

## RIFAMPICIN

**Authority Required**

***15973***

Leprosy

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**rifampicin 150 mg capsule, 100**

| 1982H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 190.50 | 25.00 | Rimycin 150 [AF] |

**rifampicin 300 mg capsule, 100**

| 1983J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 93.00 | 25.00 | Rimycin 300 [AF] |

## RIFAMPICIN

**Restricted benefit**

***16075***

Meningococcal disease

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be a carrier of the disease; **OR**
- Patient must be in close contact with people who have the disease.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

***16037***

Haemophilus influenzae type B

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be in contact with people who have the disease.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**rifampicin 100 mg/5 mL oral liquid, 60 mL**

| 8025J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 27.11 | 25.00 | Rifadin [SW] |

**rifampicin 150 mg capsule, 10**

| 1981G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 31.61 | 25.00 | Rimycin 150 [AF] |

**rifampicin 300 mg capsule, 10**

| 1984K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 22.22 | 23.76 | Rimycin 300 [AF] |

# ANTIVIRALS FOR SYSTEMIC USE

## DIRECT ACTING ANTIVIRALS

### *Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

### ACICLOVIR

**Authority Required (STREAMLINED)**

***5936***

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

**aciclovir 200 mg tablet, 25**

| 1003T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *24.24 | 25.00 | [a] Aciclovir Sandoz [HX] |

**aciclovir 200 mg tablet, 50**

| 1555W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 24.16 | 25.00 | [a] APO-Aciclovir [TX] | [a] ARX-ACICLOVIR [XT] |

### ACICLOVIR

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Authority Required (STREAMLINED)**

***5942***

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**aciclovir 200 mg tablet, 90**

| 1007B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 5 | 0.00 | 32.01 | 25.00 | [a] Aciclovir GH [GQ] | [a] Aciclovir Sandoz [HX] |
| | | | | | | [a] ACICLOVIR-WGR [WG] | [a] APO-Aciclovir [TX] |
| | | | | | | [a] ARX-ACICLOVIR [XT] | |

## ACICLOVIR

**Authority Required (STREAMLINED)**

***5967***

Herpes zoster

**Clinical criteria:**

- The treatment must be administered within 72 hours of the onset of the rash.

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

**Note** No applications for repeats will be authorised.

**Authority Required (STREAMLINED)**

***5959***

Herpes zoster ophthalmicus

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

**Note** No applications for repeats will be authorised.

**aciclovir 800 mg tablet, 35**

| 1052J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 35.72 | 25.00 | [a] Aciclovir Sandoz [HX] | [a] ACICLOVIR-WGR [WG] |
| | | | | | | [a] APO-Aciclovir [TX] | [a] ARX-ACICLOVIR [XT] |

## FAMCICLOVIR

**Authority Required (STREAMLINED)**

***5937***

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**famciclovir 250 mg tablet, 20**

| 2274Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 32.46 | 25.00 | [a] APO-Famciclovir [TX] | [a] FAMCICLOVIR-WGR [WG] |
| | | | | | | [a] Famvir [IX] | [a] Favic 250 [RW] |

## FAMCICLOVIR

**Authority Required (STREAMLINED)**

***5951***

Herpes zoster

**Clinical criteria:**

- The treatment must be administered within 72 hours of the onset of the rash.

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note** No applications for repeats will be authorised.

**famciclovir 250 mg tablet, 21**

| 8002E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 33.36 | 25.00 | [a] APO-Famciclovir [TX] | [a] Ezovir [XT] |
| | | | | | | [a] FAMCICLOVIR-WGR [WG] | [a] Famvir [IX] |
| | | | | | | [a] Favic 250 [RW] | |

## FAMCICLOVIR

**Authority Required (STREAMLINED)**

***5937***

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Note** Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**famciclovir 125 mg tablet, 40**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8092X | | | | | | | |
| NP | 1 | 1 | 0.00 | 32.46 | 25.00 | [a] APO-Famciclovir [TX] | [a] Famvir [IX] |
| | | | | | | [a] Favic 125 [RW] | |

## FAMCICLOVIR

**Authority Required (STREAMLINED)**

***5971***

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Note** Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**famciclovir 250 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8217L | | | | | | | |
| NP | 1 | 5 | 0.00 | 65.03 | 25.00 | [a] APO-Famciclovir [TX] | [a] Ezovir [XT] |
| | | | | | | [a] FAMCICLOVIR-WGR [WG] | [a] Famvir [IX] |
| | | | | | | [a] Favic 250 [RW] | |

## FAMCICLOVIR

**Authority Required (STREAMLINED)**

***5943***

Herpes zoster

**Clinical criteria:**

- Patient must be immunocompromised, **AND**
- The treatment must be administered within 72 hours of the onset of the rash.

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Note** No applications for repeats will be authorised.

**famciclovir 500 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8897G | | | | | | | |
| NP | 1 | 0 | 0.00 | 41.52 | 25.00 | [a] APO-Famciclovir [TX] | [a] FAMCICLOVIR-WGR [WG] |
| | | | | | | [a] Famvir [IX] | [a] Favic 500 [RW] |

## FAMCICLOVIR

**Authority Required (STREAMLINED)**

***5954***

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

**Clinical criteria:**

- Patient must be immunocompromised.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Authority Required (STREAMLINED)**

***5947***

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Episodic treatment

**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must have a CD4 cell count of less than 500 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Authority Required (STREAMLINED)**

***5948***

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must have CD4 cell counts of less than 150 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Authority Required (STREAMLINED)**

***5949***

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

**Clinical criteria:**

- Patient must have HIV infection, **AND**
- Patient must present with other opportunistic infections or AIDS defining tumours.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Note** Famciclovir 500 mg is not PBS-subsidised for chickenpox.

**Note** Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**famciclovir 500 mg tablet, 56**

| 8896F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 65.06 | 25.00 | [a] APO-Famciclovir [TX] | [a] Ezovir [XT] |
| | | | | | | [a] FAMCICLOVIR-WGR [WG] | [a] Famvir [IX] |
| | | | | | | [a] Favic 500 [RW] | |

## MOLNUPIRAVIR

**Note** Details of the Liverpool COVID-19 Drug interaction checker can be found at: https://www.covid19-druginteractions.org/checker

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16190***

SARS-CoV-2 infection

**Clinical criteria:**

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive nucleic acid test result; **OR**
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; **OR**
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

**Population criteria:**

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

**Authority Required (STREAMLINED)**

***16191***

SARS-CoV-2 infection

**Clinical criteria:**

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive nucleic acid test result; **OR**

- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

1. Any primary or acquired immunodeficiency including:

a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,

b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),

c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR

2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:

a. Chemotherapy or whole body radiotherapy,

b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,

c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),

d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR

3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR

4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR

5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

**Authority Required (STREAMLINED)**

***16200***

SARS-CoV-2 infection

**Clinical criteria:**

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive nucleic acid test result; **OR**
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.

For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care
2. The patient has disability with multiple comorbidities and/or frailty
3. Neurological conditions, including stroke and dementia and demyelinating conditions
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease
5. Heart failure, coronary artery disease, cardiomyopathies
6. Obesity (BMI greater than 30 $kg/m^2$)
7. Diabetes type I or II, requiring medication for glycaemic control
8. Renal impairment (eGFR less than 60mL/min)

9. Cirrhosis

10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above

11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

**Note** The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

**Authority Required (STREAMLINED)**

***16201***

SARS-CoV-2 infection

**Clinical criteria:**

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive nucleic acid test result; **OR**
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.

For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions:

1. The patient is in residential aged care,

2. The patient has disability with multiple comorbidities and/or frailty,

3. Neurological conditions, including stroke and dementia and demyelinating conditions,

4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,

5. Heart failure, coronary artery disease, cardiomyopathies,

6. Obesity (BMI greater than 30 kg/$m^2$),

7. Diabetes type I or II, requiring medication for glycaemic control,

8. Renal impairment (eGFR less than 60mL/min),

9. Cirrhosis, or

10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

**Note** The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

**molnupiravir 200 mg capsule, 40**

12910L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 1,091.36 | 25.00 | Lagevrio [MK] |

NP

## VALACICLOVIR

**Authority Required (STREAMLINED)**

***5960***

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### valaciclovir 500 mg tablet, 10

| 8133C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *22.84 | 24.38 | [a] APX-Valaciclovir [TY] | [a] Vaclovir [AF] |
| | | | | | | [a] Valaciclovir Sandoz [SZ] | [a] VALACICLOVIR-WGR [WG] |
| | | | | | | [a] Zelitrex [RF] | |
| | | | [B]5.10 | 27.94 | 24.38 | [a] Valtrex [RW] | |

## VALACICLOVIR

**Authority Required (STREAMLINED)**

***5961***

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

### valaciclovir 500 mg tablet, 30

| 8134D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 26.88 | 25.00 | [a] APX-Valaciclovir [TY] | [a] Shilova 500 [ZS] |
| | | | | | | [a] Vaclovir [AF] | [a] Valaciclovir RBX [RA] |
| | | | | | | [a] Valaciclovir Sandoz [SZ] | [a] Valaciclovir SZ [HX] |
| | | | | | | [a] VALACICLOVIR-WGR [WG] | [a] Zelitrex [RF] |
| | | | [B]2.35 | 29.23 | 25.00 | [a] Valtrex [RW] | |

## VALACICLOVIR

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority Required (STREAMLINED)**

***5940***

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

### valaciclovir 500 mg tablet, 30

| 5480K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 5 | 0.00 | 26.88 | 25.00 | [a] APX-Valaciclovir [TY] | [a] Shilova 500 [ZS] |
| | | | | | | [a] Vaclovir [AF] | [a] Valaciclovir RBX [RA] |
| | | | | | | [a] Valaciclovir Sandoz [SZ] | [a] Valaciclovir SZ [HX] |
| | | | | | | [a] VALACICLOVIR-WGR [WG] | [a] Zelitrex [RF] |
| | | | [B]2.35 | 29.23 | 25.00 | [a] Valtrex [RW] | |

## VALACICLOVIR

**Authority Required (STREAMLINED)**

***5962***

Herpes zoster

**Clinical criteria:**

- The treatment must be administered within 72 hours of the onset of the rash.

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note** No applications for repeats will be authorised.

**Authority Required (STREAMLINED)**

***5968***

Herpes zoster ophthalmicus

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.
**Note** No applications for repeats will be authorised.

**valaciclovir 500 mg tablet, 42**

| 8064K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 31.88 | 25.00 | [a] APX-Valaciclovir [TY] | [a] Vaclovir [AF] |
| | | | | | | [a] Valaciclovir RBX [RA] | [a] Valaciclovir Sandoz [SZ] |
| | | | | | | [a] VALACICLOVIR-WGR [WG] | [a] Zelitrex [RF] |
| | | | [B]2.36 | 34.24 | 25.00 | [a] Valtrex [RW] | |

***Protease inhibitors***

## NIRMATRELVIR (&) RITONAVIR

**Caution** Nirmatrelvir with ritonavir has significant drug-drug interactions. Please refer to the TGA approved Paxlovid Product Information. Prescribers and dispensers should carefully review a patient's concomitant medications including over-the-counter medications, herbal supplements, and recreational drugs.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***16155***
SARS-CoV-2 infection
**Clinical criteria:**

- Patient must have received a positive nucleic acid test result; **OR**
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; **OR**
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

**Population criteria:**

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.
Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.
Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.
This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Authority Required (STREAMLINED)**
***16223***
SARS-CoV-2 infection
**Clinical criteria:**

- Patient must have received a positive nucleic acid test result; **OR**
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:
1. Any primary or acquired immunodeficiency including:
a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,
b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),
c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR
2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:
a. Chemotherapy or whole body radiotherapy,
b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,
c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),

d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR

3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR

4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR

5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Authority Required (STREAMLINED)**

***16192***

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive nucleic acid test result; **OR**
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.

For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care

2. The patient has disability with multiple comorbidities and/or frailty

3. Neurological conditions, including stroke and dementia and demyelinating conditions

4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease

5. Heart failure, coronary artery disease, cardiomyopathies

6. Obesity (BMI greater than 30 kg/$m^2$)

7. Diabetes type I or II, requiring medication for glycaemic control

8. Renal impairment (eGFR less than 60mL/min)

9. Cirrhosis

10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above

11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Note** The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

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**Authority Required (STREAMLINED)**

***16156***

SARS-CoV-2 infection

**Clinical criteria:**

- Patient must have received a positive nucleic acid test result; **OR**
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

**Population criteria:**

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.

For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions:

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/$m^2$),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where nucleic acid testing is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

**Note** The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

**nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6**

| 12996B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 1,104.51 | 25.00 | Paxlovid [PF] |

## *Antivirals for treatment of HCV infections*

### GLECAPREVIR + PIBRENTASVIR

**Authority Required**

***10268***

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.
The application must include details of the prior treatment regimen containing an NS5A inhibitor.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

| 11344C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 17,179.03 | 25.00 | Maviret [VE] |

### GLECAPREVIR + PIBRENTASVIR

**Authority Required**

***7593***

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11353M | 1 | 1 | 0.00 | 17,179.03 | 25.00 | Maviret [VE] |
| NP | | | | | | |

## GLECAPREVIR + PIBRENTASVIR

**Authority Required**

***7615***

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11354N | 1 | 2 | 0.00 | 17,179.03 | 25.00 | Maviret [VE] |
| NP | | | | | | |

## SOFOSBUVIR + VELPATASVIR

**Authority Required**

***5969***

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11147Q | 1 | 2 | 0.00 | 12,207.36 | 25.00 | Epclusa [GI] |
| NP | | | | | | |

## SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***10248***

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.

**sofosbuvir 400 mg + velpatasvir 100 mg + voxilaprevir 100 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11658N | 1 | 2 | 0.00 | 12,207.36 | 25.00 | Vosevi [GI] |
| NP | | | | | | |

### *Antivirals for treatment of HIV infections, combinations*

## TENOFOVIR DISOPROXIL + EMTRICITABINE

**Note** Pharmaceutical benefits that have the forms tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***11143***

Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- Patient must have at least one of the following prior to having the latest PBS-subsidised prescription issued: (i) a negative HIV test result no older than 4 weeks, (ii) evidence that an HIV test has been conducted, but the result is still forthcoming.

**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30**

| 11276L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 35.22 | 25.00 | [a] CIPLA TENOFOVIR + EMTRICITABINE 300/200 [LR] | [a] TENOFOVIR/EMTRICITABINE 300/200 APX [XW] |
| | | | | | | [a] TENOFOVIR/EMTRICITABINE 300/200 ARX [XT] | [a] Tenofovir/Emtricitabine Sandoz Pharma 300/200 [HX] |

**tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30**

| 11296M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 35.22 | 25.00 | [a] Tenofovir Disoproxil Emtricitabine Viatris 300/200 [AL] |

**tenofovir disoproxil succinate 301 mg + emtricitabine 200 mg tablet, 30**

| 12542D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 35.22 | 25.00 | [a] Tenofovir/Emtricitabine Sandoz 301/200 [SZ] |

## TENOFOVIR DISOPROXIL + EMTRICITABINE

**Note** Pharmaceutical benefits that have the forms tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***18908***

Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have at least one of the following prior to having the latest PBS-subsidised prescription issued: (i) a negative HIV test result no older than 4 weeks, (ii) evidence that an HIV test has been conducted, but the result is still forthcoming.

**tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30**

| 15366R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *56.08 | 25.00 | [a] Tenofovir Disoproxil Emtricitabine Viatris 300/200 [AL] |

**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30**

| 15383P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *56.08 | 25.00 | [a] CIPLA TENOFOVIR + EMTRICITABINE 300/200 [LR] | [a] TENOFOVIR/EMTRICITABINE 300/200 APX [XW] |
| | | | | | | [a] TENOFOVIR/EMTRICITABINE 300/200 ARX [XT] | |

**tenofovir disoproxil succinate 301 mg + emtricitabine 200 mg tablet, 30**

| 15410C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *56.08 | 25.00 | [a] Tenofovir/Emtricitabine Sandoz 301/200 [SZ] |

# VACCINES

## BACTERIAL VACCINES

### *Tetanus vaccines*

## DIPHTHERIA + TETANUS VACCINE

**Note** For immunisation of adults and children aged greater than or equal to 8 years.

**diphtheria 2 units + tetanus 20 units vaccine injection, 5 x 0.5 mL syringes**

| 8783G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 92.93 | 25.00 | ADT Booster [CS] |

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## ANTINEOPLASTIC AGENTS

### ALKYLATING AGENTS

#### *Nitrogen mustard analogues*

### CHLORAMBUCIL

**chlorambucil 2 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1163F | 4 | 2 | 0.00 | *133.76 | 25.00 | Leukeran [AS] |

### CHLORMETHINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16145***

Mycosis fungoides cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be any of: (i) Stage IA, (ii) IIA, (iii) IB mycosis fungoides cutaneous T-cell lymphoma, **AND**
- The condition must have been confirmed through a diagnostic lesion biopsy from an Approved Pathology Authority, **AND**
- The condition must cover either of which: (i) no more than 10% of the patient's body surface area, (ii) no more than 25% of the patient's body surface area, **AND**
- Patient must be treated by at least one of the following prescriber types (i) dermatologist, (ii) haematologist, **AND**
- The treatment must be approved for 1 unit if the condition is no more than 10% of the patient's body surface area to provide 4 weeks of treatment per script; **OR**
- The treatment must be approved for 2 units if the condition is no more than 25% of the patient's body surface area to provide 4 weeks of treatment per script.

**Population criteria:**

- Patient must be at least 18 years of age.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

**Authority Required**

***16054***

Mycosis fungoides cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be treated by at least one of the following prescriber types (i) dermatologist, (ii) haematologist, **AND**
- The treatment must be approved for 1 unit if the condition is no more than 10% of the patient's body surface area to provide 4 weeks of treatment per script; **OR**
- The treatment must be approved for 2 units if the condition is no more than 25% of the patient's body surface area to provide 4 weeks of treatment per script.

**chlormethine 0.016% (160 microgram/g) gel, 60 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14658L | 2 | 5 | 0.00 | *3,464.42 | 25.00 | Ledaga [XT] |

### CYCLOPHOSPHAMIDE

**Restricted benefit**

***17848***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**cyclophosphamide 50 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 153.54 | 25.00 | Cyclonex [GH] |

## MELPHALAN

### melphalan 2 mg tablet, 25

| 2547C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 64.76 | 25.00 | Alkeran [AS] |

## *Alkyl sulfonates*

## BUSULFAN

### busulfan 2 mg tablet, 100

| 1128J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 78.41 | 25.00 | Myleran [AS] |

## *Nitrosoureas*

## CARMUSTINE

**Restricted benefit**

***6056***

Glioblastoma multiforme

**Clinical criteria:**

- The condition must be suspected or confirmed at the time of initial surgery.

**Note** Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

### carmustine 7.7 mg implant, 8

| 8898H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 0 | 0.00 | 11,320.68 | 25.00 | Gliadel [EI] |

## *Other alkylating agents*

## TEMOZOLOMIDE

**Restricted benefit**

***17848***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

### temozolomide 5 mg capsule, 5

| 8378Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Temozolomide [TX] | [a] Temizole 5 [AL] |
| | | | | | | [a] Temozolomide Juno [JX] | |

### temozolomide 20 mg capsule, 5

| 8379B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 26.08 | 25.00 | [a] APO-Temozolomide [TX] | [a] Temizole 20 [AL] |
| | | | | | | [a] Temozolomide Juno [JX] | |

### temozolomide 100 mg capsule, 5

| 8380C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 64.62 | 25.00 | [a] APO-Temozolomide [TX] | [a] Temizole 100 [AL] |
| | | | | | | [a] Temozolomide Juno [JX] | |

### temozolomide 140 mg capsule, 5

| 9362R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 83.68 | 25.00 | [a] APO-Temozolomide [TX] | [a] Temizole 140 [AL] |
| | | | | | | [a] Temozolomide Juno [JX] | |

### temozolomide 180 mg capsule, 5

| 2438H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 118.55 | 25.00 | [a] APO-Temozolomide [TX] | [a] Temozolomide Juno [JX] |

### temozolomide 250 mg capsule, 5

| 8381D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 134.74 | 25.00 | [a] APO-Temozolomide [TX] | [a] Temizole 250 [AL] |
| | | | | | | [a] Temozolomide Juno [JX] | |

## TEMOZOLOMIDE

**Note** Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***17854***

Glioblastoma multiforme

**Treatment criteria:**

- Patient must be undergoing concomitant radiotherapy, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**temozolomide 5 mg capsule, 5**

| 8819E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 2 | 0.00 | *27.09 | 25.00 | [a] APO-Temozolomide [TX] | [a] Temizole 5 [AL] |
| | | | | | | [a] Temozolomide Juno [JX] | |

**temozolomide 20 mg capsule, 5**

| 8820F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 2 | 0.00 | *49.53 | 25.00 | [a] APO-Temozolomide [TX] | [a] Temizole 20 [AL] |
| | | | | | | [a] Temozolomide Juno [JX] | |

**temozolomide 100 mg capsule, 5**

| 8821G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 2 | 0.00 | *167.67 | 25.00 | [a] APO-Temozolomide [TX] | [a] Temizole 100 [AL] |
| | | | | | | [a] Temozolomide Juno [JX] | |

**temozolomide 140 mg capsule, 5**

| 9361Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 2 | 0.00 | *227.73 | 25.00 | [a] APO-Temozolomide [TX] | [a] Temizole 140 [AL] |
| | | | | | | [a] Temozolomide Juno [JX] | |

**temozolomide 180 mg capsule, 5**

| 10062N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 2 | 0.00 | *336.93 | 25.00 | [a] APO-Temozolomide [TX] | [a] Temozolomide Juno [JX] |

## ANTIMETABOLITES

### *Folic acid analogues*

## METHOTREXATE

**methotrexate 2.5 mg tablet, 30**

| 1622J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.45 | 20.99 | [a] ARX-Methotrexate [XT] | [a] Chexate [OX] |
| | | | | | | [a] Methoblastin [PF] | |

**methotrexate 5 mg/2 mL injection, 5 x 2 mL vials**

| 2396D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 42.34 | 25.00 | DBL Methotrexate [PF] |

**methotrexate 10 mg tablet, 15**

| 2272N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 24.86 | 25.00 | [a] ARX-Methotrexate [XT] | [a] Chexate [OX] |
| | | | | | | [a] Methoblastin [PF] | |

**methotrexate 10 mg tablet, 10**

| 14643Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.36 | 22.90 | [a] Chexate [OX] | [a] Methoblastin [PF] |

**methotrexate 50 mg/2 mL injection, 5 x 2 mL vials**

| 2395C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 40.96 | 25.00 | DBL Methotrexate [PF] |

## METHOTREXATE

**Restricted benefit**

***5648***

Patients requiring doses greater than 20 mg per week

**methotrexate 10 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1623K NP | 1 | 2 | 0.00 | 49.35 | 25.00 | [a] ARX-Methotrexate [XT] | [a] Chexate [OX] |
| | | | | | | [a] Methoblastin [PF] | |

## METHOTREXATE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**methotrexate 50 mg/2 mL injection, 5 x 2 mL vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13882P | 2 | 5 | 0.00 | *67.56 | 25.00 | DBL Methotrexate [PF] |

### *Purine analogues*

## FLUDARABINE

**fludarabine phosphate 10 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9184J | 1 | 5 | 0.00 | 920.46 | 25.00 | Fludara [GZ] |

## MERCAPTOPURINE

**Restricted benefit**

***17848***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**mercaptopurine monohydrate 20 mg/mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10214N NP | ‡1 | 2 | 0.00 | 455.09 | 25.00 | Allmercap [LM] |

**mercaptopurine monohydrate 50 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1598D NP | 4 | 2 | 0.00 | *165.32 | 25.00 | [a] ARX-Mercaptopurine [XT] | [a] MERCAPTOPURINE-LINK [LM] |
| | | | [B]7.20 | *172.52 | 25.00 | [a] Purinethol [AS] | |

## TIOGUANINE

**tioguanine 40 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1233X | 1 | 1 | 0.00 | 190.09 | 25.00 | Lanvis [AS] |

### *Pyrimidine analogues*

## AZACITIDINE

**Caution** Oral azacitidine should not be used interchangeably with injectable azacitidine due to differences in the exposure, dose and schedule of treatment.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***14338***

Acute Myeloid Leukaemia

Treatment Phase: Treatment following intensive induction chemotherapy - Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have, for reasons not attributable to any cause other than AML, no more than 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, **AND**

- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

**azacitidine 200 mg tablet, 7**

13623B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *13,647.68 | 25.00 | Onureg [BQ] |

## AZACITIDINE

**Caution** Oral azacitidine should not be used interchangeably with injectable azacitidine due to differences in the exposure, dose and schedule of treatment.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18334***

Acute Myeloid Leukaemia

Treatment Phase: Dose escalation therapy - Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have, in order to extend the dose schedule as per the TGA-approved Product Information, between 5% to 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, in conjunction with clinical assessment, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail:

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

(c) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating the blast percentage.

All reports must be documented in the patient's medical records.

**azacitidine 300 mg tablet, 7**

13624C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 1 | 0.00 | *20,416.83 | 25.00 | Onureg [BQ] |

## AZACITIDINE

**Caution** Oral azacitidine should not be used interchangeably with injectable azacitidine due to differences in the exposure, dose and schedule of treatment.

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***14332***

Acute Myeloid Leukaemia

Treatment Phase: Treatment following intensive induction chemotherapy - Initial treatment

**Clinical criteria:**

- Patient must have demonstrated either: (i) first complete remission, (ii) complete remission with incomplete blood count recovery following intensive induction chemotherapy, **AND**
- Patient must not be a candidate for, including those who choose not to proceed to, haematopoietic stem cell transplantation, **AND**
- Patient must have, at the time of induction therapy, a cytogenetic risk classified as either: (i) intermediate-risk, (ii) poor-risk, **AND**
- Patient must not have undergone a stem cell transplant, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

A complete remission is defined as: bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood transfusions and a recovery of peripheral blood counts with peripheral neutrophil count greater than 1.0 x $10^9$/L and platelet count greater than or equal to 100 x $10^9$/L.

A complete remission with incomplete blood count recovery is defined as bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood transfusions and a recovery of peripheral blood counts with peripheral neutrophil count less than 1.0 x $10^9$/L or platelet count less than 100 x $10^9$/L.

**Authority Required**

***14338***

Acute Myeloid Leukaemia

Treatment Phase: Treatment following intensive induction chemotherapy - Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have, for reasons not attributable to any cause other than AML, no more than 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.

**azacitidine 300 mg tablet, 7**

| 13619T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *13,647.68 | 25.00 | Onureg [BQ] |

## CAPECITABINE

**Restricted benefit**

***17848***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**capecitabine 500 mg tablet, 120**

| 8362D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 61.75 | 25.00 | Xelabine [AL] |

## DECITABINE + CEDAZURIDINE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***13258***

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

**decitabine 35 mg + cedazuridine 100 mg tablet, 5**

| 13081L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 4,926.36 | 25.00 | Inqovi 35/100 [TJ] |

## DECITABINE + CEDAZURIDINE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18491***

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report, **AND**
- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

The first authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has chronic myelomonocytic leukaemia; and

(b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following reports must be documented in the patient's medical records:

(a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and

(b) full blood examination report

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 888 333.

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

PBS Authorities

GPO Box 9826

[Your capital city]

**decitabine 35 mg + cedazuridine 100 mg tablet, 5**

13133F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 4,926.36 | 25.00 | Inqovi 35/100 [TJ] |

## DECITABINE + CEDAZURIDINE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***13267***

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be myelodysplastic syndrome confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); **OR**
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), **AND**
- The condition must have up to 20% marrow blasts according to World Health Organisation (WHO) Classification.

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

(a) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR

(b) 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

(c) 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

(d) 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR

(e) Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

(a) 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

(b) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The following information must be provided by the prescriber at the time of application:

(a) The patient's International Prognostic Scoring System (IPSS) score.

The following reports must be documented in the patient's medical records:

(a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(b) full blood examination report; and

(c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS).

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***13241***

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

The following reports must be documented in the patient's medical records:

(a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and

(b) full blood examination report.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**decitabine 35 mg + cedazuridine 100 mg tablet, 5**

13087T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 4,926.36 | 25.00 | Inqovi 35/100 [TJ] |

## DECITABINE + CEDAZURIDINE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients must be avoided during treatment and for the 6-month period after cessation of treatment. Pregnancy in partners of male patients must be avoided during treatment and for the 3-month period after cessation of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***13257***

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Up to 6 cycles will be authorised.

**Authority Required**

***13165***

Chronic Myelomonocytic Leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Up to 6 cycles will be authorised.

**decitabine 35 mg + cedazuridine 100 mg tablet, 5**

13107W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 4,926.36 | 25.00 | Inqovi 35/100 [TJ] |

## TRIFLURIDINE + TIPIRACIL

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***18518***
Metastatic colorectal cancer
Treatment Phase: Initial treatment
**Clinical criteria:**

- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must have been previously treated with or not considered a candidate for treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-vascular endothelial growth factor (anti-VEGF) agent and an anti-epidermal growth factor receptor (anti-EGFR) agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment is initiated.

**Authority Required (STREAMLINED)**
***8183***
Metastatic colorectal cancer
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**trifluridine 15 mg + tipiracil 6.14 mg tablet, 20**

| 11507P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 2 | 0.00 | *2,322.00 | 25.00 | Lonsurf 15/6.14 [SE] |

**trifluridine 20 mg + tipiracil 8.19 mg tablet, 20**

| 11524M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 2 | 0.00 | *4,042.96 | 25.00 | Lonsurf 20/8.19 [SE] |

## TRIFLURIDINE + TIPIRACIL

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***18515***
Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction
Treatment Phase: Initial treatment
**Clinical criteria:**

- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must have previously received at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum and either a taxane or irinotecan, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment is initiated.

**Authority Required (STREAMLINED)**
***10310***
Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**trifluridine 15 mg + tipiracil 6.14 mg tablet, 20**

| 12056M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 2 | 0.00 | *2,322.00 | 25.00 | Lonsurf 15/6.14 [SE] |

**trifluridine 20 mg + tipiracil 8.19 mg tablet, 20**

| 12033H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 2 | 0.00 | *4,042.96 | 25.00 | Lonsurf 20/8.19 [SE] |

## PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

### *Vinca alkaloids and analogues*

## VINORELBINE

**Authority Required**

***18015***

Advanced breast cancer

**Clinical criteria:**

- Patient must have failed standard prior therapy, which includes an anthracycline.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Authority Required**

***17855***

Locally advanced or metastatic non-small cell lung cancer

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**vinorelbine 20 mg capsule, 1**

| 9009E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 20 | 2 | 0.00 | *845.64 | 25.00 | Velabine [XT] |

**vinorelbine 30 mg capsule, 1**

| 9010F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 16 | 2 | 0.00 | *1,018.52 | 25.00 | Velabine [XT] |

### *Podophyllotoxin derivatives*

## ETOPOSIDE

**etoposide 50 mg capsule, 20**

| 1396L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 437.69 | 25.00 | Vepesid [LM] |

**etoposide 100 mg capsule, 10**

| 1389D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 382.47 | 25.00 | Vepesid [LM] |

## PROTEIN KINASE INHIBITORS

### *BCR-ABL tyrosine kinase inhibitors*

## ASCIMINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***19234***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment for patients without T315I mutation

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; **OR**
- Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a response at 12-monthly intervals of either: (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**asciminib 20 mg tablet, 60**

| 13268H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 6,265.11 | 25.00 | Scemblix [NV] |

**asciminib 40 mg tablet, 60**

| 13259W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 6,265.11 | 25.00 | Scemblix [NV] |

## ASCIMINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***19260***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial PBS-subsidised treatment for patients without T315I mutation

**Clinical criteria:**

- The condition must not be in the blast phase, **AND**
- Patient must have experienced an inadequate response to an adequate trial of at least two tyrosine kinase inhibitors; **OR**
- Patient must have experienced intolerance, not an inadequate response, to at least two tyrosine kinase inhibitors; **OR**
- Patient must have experienced an inadequate response to an adequate trial of at least one tyrosine kinase inhibitor with intolerance to at least another tyrosine kinase inhibitor, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Blast phase defined according to the latest WHO criteria.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**asciminib 20 mg tablet, 60**

| 13248G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 6,265.11 | 25.00 | Scemblix [NV] |

**asciminib 40 mg tablet, 60**

| 13264D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 6,265.11 | 25.00 | Scemblix [NV] |

## ASCIMINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***19277***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial PBS-subsidised treatment for patients with T315I mutation

**Clinical criteria:**

- The condition must not be in the blast phase, **AND**
- Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report, **AND**
- The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; **OR**
- The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), **AND**
- Patient must have experienced an inadequate response to an adequate trial of at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority; **OR**
- Patient must have experienced intolerance, not an inadequate response, to at least one tyrosine kinase inhibitor, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or

(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and

(iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and

(iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

Blast phase defined according to the latest WHO criteria.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**Authority Required**

***19218***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing Treatment for patients with T315I mutation

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; **OR**
- Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

The continuing application for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a major cytogenetic response [see Note explaining definitions of response]; or

(ii) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response].

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy

### asciminib 40 mg tablet, 60

| 13260X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 5 | 0.00 | *30,888.09 | 25.00 | Scemblix [NV] |

## DASATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***19225***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be responding to treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**

- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**dasatinib 20 mg tablet, 60**

| 12869H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 177.22 | 25.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib Sandoz [SZ] | [a] Dasatinib SUN [RA] |
| | | | | | | [a] DASATINIB-TEVA [TB] | [a] Dasatinib Viatris [AL] |
| | | | | | | [a] MSN Dasatinib [VM] | [a] Sprycel [BQ] |

**dasatinib 50 mg tablet, 60**

| 12843Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 285.85 | 25.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib Sandoz [SZ] | [a] Dasatinib SUN [RA] |
| | | | | | | [a] DASATINIB-TEVA [TB] | [a] Dasatinib Viatris [AL] |
| | | | | | | [a] MSN Dasatinib [VM] | [a] Sprycel [BQ] |

**dasatinib 70 mg tablet, 60**

| 12890K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 351.66 | 25.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib Sandoz [SZ] | [a] Dasatinib SUN [RA] |
| | | | | | | [a] DASATINIB-TEVA [TB] | [a] Dasatinib Viatris [AL] |
| | | | | | | [a] MSN Dasatinib [VM] | [a] Sprycel [BQ] |

**dasatinib 100 mg tablet, 30**

| 12889J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 285.85 | 25.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib Sandoz [SZ] | [a] Dasatinib SUN [RA] |
| | | | | | | [a] DASATINIB-TEVA [TB] | [a] Dasatinib Viatris [AL] |
| | | | | | | [a] MSN Dasatinib [VM] | [a] Sprycel [BQ] |

## DASATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***19223***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- Patient must not have previously experienced an inadequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**dasatinib 20 mg tablet, 60**

| 1354G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 177.22 | 25.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib Sandoz [SZ] | [a] Dasatinib SUN [RA] |
| | | | | | | [a] DASATINIB-TEVA [TB] | [a] Dasatinib Viatris [AL] |
| | | | | | | [a] MSN Dasatinib [VM] | [a] Sprycel [BQ] |

**dasatinib 50 mg tablet, 60**

| 1381Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 285.85 | 25.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib Sandoz [SZ] | [a] Dasatinib SUN [RA] |
| | | | | | | [a] DASATINIB-TEVA [TB] | [a] Dasatinib Viatris [AL] |
| | | | | | | [a] MSN Dasatinib [VM] | [a] Sprycel [BQ] |

**dasatinib 70 mg tablet, 60**

| 1415L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 351.66 | 25.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib Sandoz [SZ] | [a] Dasatinib SUN [RA] |
| | | | | | | [a] DASATINIB-TEVA [TB] | [a] Dasatinib Viatris [AL] |
| | | | | | | [a] MSN Dasatinib [VM] | [a] Sprycel [BQ] |

**dasatinib 100 mg tablet, 30**

| 1416M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 285.85 | 25.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib Sandoz [SZ] | [a] Dasatinib SUN [RA] |
| | | | | | | [a] DASATINIB-TEVA [TB] | [a] Dasatinib Viatris [AL] |
| | | | | | | [a] MSN Dasatinib [VM] | [a] Sprycel [BQ] |

## DASATINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17879***

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed treatment with chemotherapy, **AND**
- Patient must have failed treatment with imatinib, **AND**
- Patient must have failed an allogeneic haemopoietic stem cell transplantation if applicable.

**Treatment criteria:**

- Must be treated by a medical practitioner.

Failure of treatment is defined as either:

(i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;

(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;

(iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

**Note** Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17984***

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy following treatment with imatinib, **AND**
- The condition must not have progressed.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Note** Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***17821***

Acute lymphoblastic leukaemia

Treatment Phase: Induction and Consolidation therapy

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner.

The authority application must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided).

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17817***

Acute lymphoblastic leukaemia

Treatment Phase: Maintenance of first complete remission

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with imatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug that is occurring within the first 24 months from the first administered dose; **OR**
- Patient must be undergoing treatment with this drug that is occurring beyond the first 24 months from the first administered dose - the patient meets the conditions as outlined below, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

Conditions for PBS-subsidy beyond 24 months of treatment:

On the first occasion an authority application extends PBS-subsidy beyond 24 months, confirm that:

1) The condition is expressing the Philadelphia chromosome,

2) Measurable residual disease (MRD) is present,

3) MRD has been confirmed in at least one of: (i) marrow, (ii) peripheral blood,

4) MRD has been confirmed within the preceding 6 months of this authority application,

5) MRD has been ascertained by at least one of: (i) a molecular method, (ii) flow cytometry,

6) Allogenic stem cell transplantation is considered by the prescriber to be unsuitable for the patient.

For any subsequent authority application beyond the 24 month time mark, confirm that MRD has been detected within the preceding 12 months of this subsequent authority application. Where MRD has since become undetectable, confirm that PBS-subsidy has not exceeded a further 12 months duration from the date that MRD became undetectable.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**dasatinib 20 mg tablet, 60**

| 9125G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 177.22 | 25.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib Sandoz [SZ] | [a] Dasatinib SUN [RA] |
| | | | | | | [a] DASATINIB-TEVA [TB] | [a] Dasatinib Viatris [AL] |
| | | | | | | [a] MSN Dasatinib [VM] | [a] Sprycel [BQ] |

**dasatinib 50 mg tablet, 60**

| 9126H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 285.85 | 25.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib Sandoz [SZ] | [a] Dasatinib SUN [RA] |
| | | | | | | [a] DASATINIB-TEVA [TB] | [a] Dasatinib Viatris [AL] |
| | | | | | | [a] MSN Dasatinib [VM] | [a] Sprycel [BQ] |

**dasatinib 70 mg tablet, 60**

| 9127J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 351.66 | 25.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib Sandoz [SZ] | [a] Dasatinib SUN [RA] |
| | | | | | | [a] DASATINIB-TEVA [TB] | [a] Dasatinib Viatris [AL] |
| | | | | | | [a] MSN Dasatinib [VM] | [a] Sprycel [BQ] |

**dasatinib 100 mg tablet, 30**

| 9343R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 285.85 | 25.00 | [a] Dasatinib ARX [XT] | [a] Dasatinib Dr.Reddy's [RI] |
| | | | | | | [a] Dasatinib Sandoz [SZ] | [a] Dasatinib SUN [RA] |
| | | | | | | [a] DASATINIB-TEVA [TB] | [a] Dasatinib Viatris [AL] |
| | | | | | | [a] MSN Dasatinib [VM] | [a] Sprycel [BQ] |

## IMATINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Authority Required**

***9238***

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient's medical records.

**imatinib 100 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5443L | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12759M | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority Required**

***9238***

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient's medical records.

**imatinib 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5444M | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12681K | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***9240***

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be unresectable; **OR**
- The condition must be locally recurrent; **OR**
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

### imatinib 100 mg tablet, 60

9172R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

### imatinib 100 mg capsule, 60

10942X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***9240***

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be unresectable; **OR**
- The condition must be locally recurrent; **OR**
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

### imatinib 400 mg tablet, 30

9173T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

### imatinib 400 mg capsule, 30

10933K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | [a] Imatinib GH [GQ] | |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***9274***

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a full blood examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

| 9174W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

| 10941W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***9274***

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a full blood examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

| 9175X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

| 10925B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***9276***

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; **OR**
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); **OR**
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; **OR**
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; **OR**
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

| 9176Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

| 10918P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***9276***

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; **OR**
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); **OR**
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; **OR**
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; **OR**
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

| 9177B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

| 10939R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***9204***

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; **OR**
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.

The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

| 9178C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

| 10940T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***9204***

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; **OR**
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.

The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

| 9179D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

| 10921T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17884***

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be unresectable; **OR**
- The condition must be locally recurrent; **OR**
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

| 11753N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

| 11776T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17960***

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 400 mg capsule, 30**

| 11756R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

**imatinib 400 mg tablet, 30**

| 11765F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17960***

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be PDGFRB fusion gene-positive, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 100 mg capsule, 60**

| 11757T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

**imatinib 100 mg tablet, 60**

| 11769K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17885***

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

| 11758W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

| 11763D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17887***

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

| 11762C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

| 11777W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17884***

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be unresectable; **OR**
- The condition must be locally recurrent; **OR**
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 400 mg capsule, 30**

| 11764E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

**imatinib 400 mg tablet, 30**

| 11786H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17885***

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 100 mg capsule, 60**

| 11770L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

**imatinib 100 mg tablet, 60**

| 11781C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17887***

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 400 mg capsule, 30**

| 11779Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

**imatinib 400 mg tablet, 30**

| 11785G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required (STREAMLINED)**

***17890***

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), **AND**
- Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**imatinib 100 mg tablet, 60**

| 11784F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

| 12710Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required (STREAMLINED)**

***17890***

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), **AND**
- Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**imatinib 400 mg tablet, 30**

| 11788K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

| 12711B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

## IMATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17886***

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

**imatinib 600 mg tablet, 30**

| 12919Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 544.47 | 25.00 | Imatab [JU] |

## IMATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***17884***
Dermatofibrosarcoma protuberans
Treatment Phase: Continuing treatment
**Clinical criteria:**

- The condition must be unresectable; **OR**
- The condition must be locally recurrent; **OR**
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

| 12923E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 544.47 | 25.00 | Imatab [JU] |

## IMATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**
***9240***
Dermatofibrosarcoma protuberans
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must be unresectable; **OR**
- The condition must be locally recurrent; **OR**
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

| 12927J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 544.47 | 25.00 | Imatab [JU] |

## IMATINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Authority Required**
***9319***
Malignant gastrointestinal stromal tumour
Treatment Phase: Initial Treatment
**Clinical criteria:**

- The condition must be metastatic; **OR**
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**

- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9111M | 1 | 2 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12709X | 1 | 2 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Authority Required**

***9319***

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

**Clinical criteria:**

- The condition must be metastatic; **OR**
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9112N | 1 | 2 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12754G | 1 | 2 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17826***

Acute lymphoblastic leukaemia

Treatment Phase: Maintenance of first complete remission

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine, **AND**
- Patient must be undergoing treatment with this drug that is occurring within the first 24 months from the first administered dose; **OR**
- Patient must be undergoing treatment with this drug that is occurring beyond the first 24 months from the first administered dose - the patient meets the conditions as outlined below.

Conditions for PBS-subsidy beyond 24 months of treatment:

On the first occasion an authority application extends PBS-subsidy beyond 24 months, by annotating the prescription with the Streamlined Authority Required code, the prescriber is declaring that:

1) The condition is expressing the Philadelphia chromosome,

2) Measurable residual disease (MRD) is present,

3) MRD has been confirmed in at least one of: (i) marrow, (ii) peripheral blood,

4) MRD has been confirmed within the preceding months of this authority application,

5) MRD has been ascertained by at least one of: (i) a molecular method, (ii) flow cytometry,

6) Allogenic stem cell transplantation is considered by the prescriber to be unsuitable for the patient.

For any subsequent authority application beyond the 24 month time mark, confirm that MRD has been detected within the preceding 12 months of this subsequent authority application. Where MRD has since become undetectable, confirm that PBS-subsidy has not exceeded a further 12 months duration from the date that MRD became undetectable.

**imatinib 400 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11771M NP | 1 | 2 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

**imatinib 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11789L NP | 1 | 2 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17886***

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

**imatinib 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11778X NP | 1 | 2 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12723P NP | 1 | 2 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17826***

Acute lymphoblastic leukaemia

Treatment Phase: Maintenance of first complete remission

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine, **AND**
- Patient must be undergoing treatment with this drug that is occurring within the first 24 months from the first administered dose; **OR**
- Patient must be undergoing treatment with this drug that is occurring beyond the first 24 months from the first administered dose - the patient meets the conditions as outlined below.

Conditions for PBS-subsidy beyond 24 months of treatment:

On the first occasion an authority application extends PBS-subsidy beyond 24 months, by annotating the prescription with the Streamlined Authority Required code, the prescriber is declaring that:

1) The condition is expressing the Philadelphia chromosome,
2) Measurable residual disease (MRD) is present,
3) MRD has been confirmed in at least one of: (i) marrow, (ii) peripheral blood,
4) MRD has been confirmed within the preceding months of this authority application,
5) MRD has been ascertained by at least one of: (i) a molecular method, (ii) flow cytometry,
6) Allogenic stem cell transplantation is considered by the prescriber to be unsuitable for the patient.

For any subsequent authority application beyond the 24 month time mark, confirm that MRD has been detected within the preceding 12 months of this subsequent authority application. Where MRD has since become undetectable, confirm that PBS-subsidy has not exceeded a further 12 months duration from the date that MRD became undetectable.

**imatinib 100 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11780B | | | | | | | |
| NP | 1 | 2 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11783E | | | | | | | |
| NP | 1 | 2 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17886***

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

**imatinib 100 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11787J | | | | | | | |
| NP | 1 | 2 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12722N | | | | | | | |
| NP | 1 | 2 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***19225***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be responding to treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**imatinib 600 mg tablet, 30**

| 12912N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 544.47 | 25.00 | Imatab [JU] |

## IMATINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***12685***

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be metastatic; **OR**
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The condition must have not achieved a response with this drug at a dose of 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

| 12926H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 544.47 | 25.00 | Imatab [JU] |

## IMATINIB

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16238***

Acute lymphoblastic leukaemia

Treatment Phase: Induction and Consolidation therapy

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL, **AND**

- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9123E | 1 | 2 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10924Y | 1 | 2 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16238***

Acute lymphoblastic leukaemia

Treatment Phase: Induction and Consolidation therapy

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9124F | 1 | 2 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10917N | 1 | 2 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

## IMATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***19225***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be responding to treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**imatinib 400 mg tablet, 30**

| 11752M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

| 11772N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

## IMATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***19225***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be responding to treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**imatinib 100 mg tablet, 60**

| 11775R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

| 11782D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16238***

Acute lymphoblastic leukaemia

Treatment Phase: Induction and Consolidation therapy

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids, **AND**
- Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

| 12911M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 544.47 | 25.00 | Imatab [JU] |

## IMATINIB

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17826***

Acute lymphoblastic leukaemia

Treatment Phase: Maintenance of first complete remission

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine, **AND**
- Patient must be undergoing treatment with this drug that is occurring within the first 24 months from the first administered dose; **OR**
- Patient must be undergoing treatment with this drug that is occurring beyond the first 24 months from the first administered dose - the patient meets the conditions as outlined below.

Conditions for PBS-subsidy beyond 24 months of treatment:

On the first occasion an authority application extends PBS-subsidy beyond 24 months, by annotating the prescription with the Streamlined Authority Required code, the prescriber is declaring that:

1) The condition is expressing the Philadelphia chromosome,

2) Measurable residual disease (MRD) is present,

3) MRD has been confirmed in at least one of: (i) marrow, (ii) peripheral blood,

4) MRD has been confirmed within the preceding months of this authority application,

5) MRD has been ascertained by at least one of: (i) a molecular method, (ii) flow cytometry,

6) Allogenic stem cell transplantation is considered by the prescriber to be unsuitable for the patient.

For any subsequent authority application beyond the 24 month time mark, confirm that MRD has been detected within the preceding 12 months of this subsequent authority application. Where MRD has since become undetectable, confirm that PBS-subsidy has not exceeded a further 12 months duration from the date that MRD became undetectable.

**imatinib 600 mg tablet, 30**

| 12920B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 544.47 | 25.00 | Imatab [JU] |

## IMATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***19223***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- Patient must not have previously experienced an inadequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**imatinib 600 mg tablet, 30**

| 12935T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 544.47 | 25.00 | Imatab [JU] |

## IMATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***19223***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- Patient must not have previously experienced an inadequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**imatinib 100 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9113P | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |
| | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 100 mg capsule, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10915L | 1 | 5 | 0.00 | 97.83 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |

## IMATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***19223***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- Patient must not have previously experienced an inadequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**imatinib 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9114Q | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] Gilmat [CR] | [a] Glivec [NV] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9114Q | | | | | | [a] Imanib [AF] | [a] IMATINIB RBX [RA] |
| | | | | | | [a] Imatinib Sandoz [SZ] | [a] Imatinib-Teva [TB] |

**imatinib 400 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10916M | 1 | 5 | 0.00 | 184.64 | 25.00 | [a] ARX-IMATINIB [XT] | [a] IMATINIB-DRLA [RZ] |
| | | | | | | [a] Imatinib GH [GQ] | |

## NILOTINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***19225***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be responding to treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**nilotinib 150 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12868G NP | 1 | 5 | 0.00 | 2,917.49 | 25.00 | [a] Ceahani [NM] | [a] MSN-NILOTINIB [HK] |
| | | | | | | [a] NILOTAS [CR] | [a] Tasigna [NV] |

**nilotinib 200 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12858R NP | 1 | 5 | 0.00 | 3,822.52 | 25.00 | [a] Ceahani [NM] | [a] MSN-NILOTINIB [HK] |
| | | | | | | [a] NILOTAS [CR] | [a] Tasigna [NV] |

## NILOTINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***19223***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- Patient must not have previously experienced an inadequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.

**nilotinib 150 mg capsule, 120**

1309X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 2,917.49 | 25.00 | [a] Ceahani [NM] | [a] MSN-NILOTINIB [HK] |
| | | | | | [a] NILOTAS [CR] | [a] Tasigna [NV] |

**nilotinib 200 mg capsule, 120**

9171Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 3,822.52 | 25.00 | [a] Ceahani [NM] | [a] MSN-NILOTINIB [HK] |
| | | | | | [a] NILOTAS [CR] | [a] Tasigna [NV] |

## PONATINIB

**Authority Required**

***18039***

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be expressing the T315I mutation, **AND**
- Patient must have failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor, **AND**
- Patient must have failed allogeneic haemopoietic stem cell transplantation (where appropriate).

**Treatment criteria:**

- Must be treated by a medical practitioner.

Failure of treatment is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy, with or without another tyrosine kinase inhibitor;

2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy, with or without another tyrosine kinase inhibitor;

3. Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The authority application must be made in writing and must include:

1. details of the proposed prescription; and

2. a completed Acute Lymphoblastic Leukaemia - ponatinib Initial PBS authority application form; and

3. a signed patient acknowledgement; and

4. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript; and evidence of the T315I mutation. The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***17834***

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have progressive disease.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Note** Authority applications for continuing treatment may be made by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ponatinib 15 mg tablet, 60**

| 10523W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 5,295.37 | 25.00 | Iclusig [TK] |

**ponatinib 45 mg tablet, 30**

| 10524X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 5,957.65 | 25.00 | Iclusig [TK] |

## PONATINIB

**Authority Required**

***17835***

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed prior treatment with PBS-subsidised dasatinib for this condition; **OR**
- Patient must have developed intolerance to PBS-subsidised dasatinib of a severity requiring treatment withdrawal.

**Treatment criteria:**

- Must be treated by a medical practitioner.

Failure of treatment with dasatinib is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with PBS-subsidised dasatinib for this condition; or

2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by PBS-subsidised dasatinib for this condition; or

3. Rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission; OR rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

The authority application must be made in writing and must include:

1. details of the proposed prescription; and

2. a completed Acute Lymphoblastic Leukaemia ponatinib PBS Authority Application - Supporting Information Form; and

3. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided; or

4. pathology reports documenting rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition. The date of the relevant pathology report(s) need(s) to be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18030***

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ponatinib 15 mg tablet, 60**

| 11454W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 5,295.37 | 25.00 | Iclusig [TK] |

**ponatinib 45 mg tablet, 30**

| 11453T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 5,957.65 | 25.00 | Iclusig [TK] |

## PONATINIB

**Note TREATMENT OF PATIENTS WITH CHRONIC MYELOID LEUKAEMIA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for chronic myeloid leukaemia (CML).

Where the term TKI agent appears in the following notes and restrictions it refers to imatinib, dasatinib, nilotinib, ponatinib or asciminib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy.

Where a patient has previously received PBS-subsidised treatment with a TKI agent, no approval will be granted for PBS-subsidised re-treatment of chronic myeloid leukaemia where that patient has at any time not met the response criteria whilst being treated with that TKI agent.

For continuing applications patients must demonstrate a response to PBS-subsidised treatment and a pathology report demonstrating the patient has responded to the initial course of treatment must be documented in the patient's medical records.

**Note** 1. Authority approval requirements.

Response criteria to treatment with ponatinib:

For the purposes of assessing response to PBS-subsidised treatment with ponatinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be conducted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be conducted. The cytogenetic or peripheral blood quantitative PCR analyses must be conducted within 18 months of the commencement of treatment with ponatinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with this drug).

Thereafter, at no greater than 12 month intervals a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% must be sustained to receive continuing treatments with this drug.

2. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006).

3. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***19255***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial PBS-subsidised treatment for patients without T315I mutation

**Clinical criteria:**

- Patient must have experienced an inadequate response to an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; **OR**
- Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have experienced an inadequate response to an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority; **OR**
- Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or

(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and

(iii) where there has been a loss of response to dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

All reports must be documented in the patient's medical records

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***19246***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial PBS-subsidised treatment for patients with T315I mutation

**Clinical criteria:**

- Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or

(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and

(iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***19226***

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; **OR**
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1% on the international scale in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

A pathology report demonstrating the patient's cytogenetic response or a peripheral blood level of BCR-ABL must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ponatinib 15 mg tablet, 60**

| 10520Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,295.37 | 25.00 | Iclusig [TK] |

**ponatinib 45 mg tablet, 30**

| 10530F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,957.65 | 25.00 | Iclusig [TK] |

## *Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors*

### AFATINIB

**Authority Required (STREAMLINED)**

***7613***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**Note** Special Pricing Arrangements apply.

**afatinib 20 mg tablet, 28**

| 11336P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 2,771.92 | 25.00 | Giotrif [BY] |

**afatinib 30 mg tablet, 28**

| 11348G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 2,771.92 | 25.00 | Giotrif [BY] |

**afatinib 40 mg tablet, 28**

| 11347F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 2,771.92 | 25.00 | Giotrif [BY] |

## AFATINIB

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16404***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); **OR**
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material
- Patient must not have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) exon 20 insertion mutation.

### afatinib 20 mg tablet, 28

| 11335N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 2,771.92 | 25.00 | Giotrif [BY] |

### afatinib 30 mg tablet, 28

| 11341X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 2,771.92 | 25.00 | Giotrif [BY] |

### afatinib 40 mg tablet, 28

| 11359W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 2,771.92 | 25.00 | Giotrif [BY] |

## ERLOTINIB

**Authority Required**

***16404***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); **OR**
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material
- Patient must not have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) exon 20 insertion mutation.

### erlotinib 25 mg tablet, 30

| 10022L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 123.90 | 25.00 | [a] ERLOTINIB ARX [XT] | [a] Erlotinib Sandoz [SZ] |

### erlotinib 100 mg tablet, 30

| 10020J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 425.08 | 25.00 | [a] ERLOTINIB ARX [XT] | [a] Erlotinib Sandoz [SZ] |

### erlotinib 150 mg tablet, 30

| 10014C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 523.65 | 25.00 | [a] ERLOTINIB ARX [XT] | [a] Erlotinib Sandoz [SZ] |

## ERLOTINIB

**Authority Required (STREAMLINED)**

***4600***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014, **AND**
- Patient must not have progressive disease.

**Population criteria:**

- Patient must have a wild type epidermal growth factor receptor (EGFR) gene; **OR**
- Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

**erlotinib 25 mg tablet, 30**

| 10028T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 123.90 | 25.00 | [a] ERLOTINIB ARX [XT] | [a] Erlotinib Sandoz [SZ] |

**erlotinib 100 mg tablet, 30**

| 10019H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 425.08 | 25.00 | [a] ERLOTINIB ARX [XT] | [a] Erlotinib Sandoz [SZ] |

**erlotinib 150 mg tablet, 30**

| 10025P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 523.65 | 25.00 | [a] ERLOTINIB ARX [XT] | [a] Erlotinib Sandoz [SZ] |

## ERLOTINIB

**Authority Required (STREAMLINED)**

***7446***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have progressive disease.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**erlotinib 25 mg tablet, 30**

| 11263T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 123.90 | 25.00 | [a] ERLOTINIB ARX [XT] | [a] Erlotinib Sandoz [SZ] |

**erlotinib 100 mg tablet, 30**

| 11260P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 425.08 | 25.00 | [a] ERLOTINIB ARX [XT] | [a] Erlotinib Sandoz [SZ] |

**erlotinib 150 mg tablet, 30**

| 11259N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 523.65 | 25.00 | [a] ERLOTINIB ARX [XT] | [a] Erlotinib Sandoz [SZ] |

## GEFITINIB

**Authority Required**

***16404***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); **OR**
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material
- Patient must not have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) exon 20 insertion mutation.

**gefitinib 250 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8769M | 1 | 3 | 0.00 | 521.91 | 25.00 | Cipla Gefitinib [LR] |

## GEFITINIB

**Authority Required (STREAMLINED)**

***7447***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have progressive disease.

**gefitinib 250 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11264W | 1 | 3 | 0.00 | 521.91 | 25.00 | Cipla Gefitinib [LR] |

## OSIMERTINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18888***

Non-small cell lung cancer (NSCLC)

**Clinical criteria:**

- Patient must be each of: (i) initiating treatment with this drug; (ii) have not previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be continuing treatment with this drug for this condition, with an absence of further disease progression while being treated with this drug, **AND**
- Patient must have/have had a WHO performance status of no greater than 2 at treatment initiation with this drug for this condition, **AND**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**Population criteria:**

- Patient must not have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) exon 20 insertion mutation.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

PBS-subsidised treatment with this drug is restricted to once per lifetime at any disease stage for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Prescribers must refer to this drug's approved Therapeutic Goods Administration (TGA) Product Information (PI) for the relevant dosing regimens and treatment duration for the specific stage of NSCLC.

For patients receiving treatment with this drug as adjuvant therapy, treatment must cease upon disease progression, or after the completion of three years from the first administered dose, whichever comes first.

**osimertinib 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15378J NP | 1 | 5 | 0.00 | 7,700.25 | 25.00 | Tagrisso [AP] |

**osimertinib 80 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15392D NP | 1 | 5 | 0.00 | 7,700.25 | 25.00 | Tagrisso [AP] |

### *B-Raf serine-threonine kinase (BRAF) inhibitors*

## DABRAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***10157***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; **OR**
- Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma, **AND**
- Patient must have a WHO performance status of 2 or less.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**dabrafenib 50 mg capsule, 120**

| 2963Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 4,889.12 | 25.00 | Tafinlar [NV] |

**dabrafenib 75 mg capsule, 120**

| 2846T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 7,267.49 | 25.00 | Tafinlar [NV] |

## DABRAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17286***

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Clinical criteria:**

- Patient must have/have had a WHO performance status of no greater than 2 at treatment initiation with this drug for this condition, **AND**
- The condition must be positive for a BRAF V600E mutation, **AND**
- Patient must be receiving trametinib and dabrafenib concomitantly for this condition.

**Treatment criteria:**

- Patient must be undergoing initial treatment with this drug; **OR**
- Patient must be undergoing continuing treatment with this drug, with an absence of further disease progression while being treated with this drug; **OR**
- Patient must be undergoing non-PBS-subsidised treatment with this drug for this PBS indication, with an absence of further disease progression since commencing non-PBS-subsidised supply.

**dabrafenib 50 mg capsule, 120**

| 15056K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 4,889.12 | 25.00 | Tafinlar [NV] |

**dabrafenib 75 mg capsule, 120**

| 15055J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 7,267.49 | 25.00 | Tafinlar [NV] |

## DABRAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17950***

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**

- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must commence within 12 weeks of complete resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Authority Required**

***17915***

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection, **AND**
- Patient must not have experienced disease recurrence, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**dabrafenib 50 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11820D NP | 1 | 3 | 0.00 | 4,889.12 | 25.00 | Tafinlar [NV] |

**dabrafenib 75 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11823G NP | 1 | 3 | 0.00 | 7,267.49 | 25.00 | Tafinlar [NV] |

## DABRAFENIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17949***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**dabrafenib 50 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2954L NP | 1 | 5 | 0.00 | 4,889.12 | 25.00 | Tafinlar [NV] |

**dabrafenib 75 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10003L NP | 1 | 5 | 0.00 | 7,267.49 | 25.00 | Tafinlar [NV] |

## DABRAFENIB

**Note** Dabrafenib is available as capsules and dispersible tablets. Caution is advised when consideration is given to changing formulations as the formulations are not bioequivalent. Frequent switching between formulations is discouraged.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16385***

Paediatric high grade glioma
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must be World Health Organisation (WHO) grade 3 or 4, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have either a: (i) Karnofsky, (ii) Lansky performance score of at least 50%, **AND**
- Patient must have relapsed or progressed following frontline therapy; **OR**
- Patient must have failed to respond to frontline therapy, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

**Population criteria:**

- Patient must have been aged between 12 months to 18 years at diagnosis.

**Note** A review and validation of the Karnofsky performance status scale can be found as a free access article here:
Mor, V., Laliberte, L., Morris, J.N. and Wiemann, M. (1984), The Karnofsky performance status scale: An examination of its reliability and validity in a research setting. Cancer, 53: 2002-2007. https://doi.org/10.1002/1097-0142(19840501)53:9<2002::AID-CNCR2820530933>3.0.CO;2-W

**Note** The original publication and validation of the Lansky performance status scale can be found as a free access article here:
Lansky, S.B., List, M.A., Lansky, L.L., Ritter-Sterr, C. and Miller, D.R. (1987), The measurement of performance in childhood cancer patients. Cancer, 60: 1651-1656. https://doi.org/10.1002/1097-0142(19871001)60:7<1651::AID-CNCR2820600738>3.0.CO;2-J

**dabrafenib 10 mg dispersible tablet, 2 x 210**

| 14752K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 1 | 0.00 | *6,814.82 | 25.00 | Tafinlar [NV] |

**dabrafenib 50 mg capsule, 120**

| 14760W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 1 | 0.00 | *9,668.88 | 25.00 | Tafinlar [NV] |

**dabrafenib 75 mg capsule, 120**

| 14766E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 7,267.49 | 25.00 | Tafinlar [NV] |

## DABRAFENIB

**Note** Dabrafenib is available as capsules and dispersible tablets. Caution is advised when consideration is given to changing formulations as the formulations are not bioequivalent. Frequent switching between formulations is discouraged.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**
***16378***
Paediatric high grade glioma
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have either: (i) stable, (ii) responding disease based on the Response Assessment in Neuro-Oncology (RANO) criteria, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

**Note** Response in the proposed restrictions is assessed using the Response Assessment for Neuro-Oncology (RANO) 2017 criteria:
Wen PY, Chang SM, Van den Bent MJ, Vogelbaum MA, Macdonald DR, Lee EQ. Response Assessment in Neuro-Oncology Clinical Trials. J Clin Oncol. 2017;35(21): 2439-2449. doi:10.1200/JCO.2017.72.7511

**dabrafenib 10 mg dispersible tablet, 2 x 210**

| 14753L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *6,814.82 | 25.00 | Tafinlar [NV] |

**dabrafenib 50 mg capsule, 120**

| 14755N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *9,668.88 | 25.00 | Tafinlar [NV] |

**dabrafenib 75 mg capsule, 120**

| 14757Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 7,267.49 | 25.00 | Tafinlar [NV] |

## DABRAFENIB

**Note** Dabrafenib is available as capsules and dispersible tablets. Caution is advised when consideration is given to changing formulations as the formulations are not bioequivalent. Frequent switching between formulations is discouraged.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16377***

Paediatric low grade glioma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The condition must have progressed following surgical excision; **OR**
- The condition must not be amenable to surgery with risk of neurological impairment following progression, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have either a: (i) Karnofsky, (ii) Lansky performance score of at least 50%, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

**Population criteria:**

- Patient must have been aged between 12 months to 18 years at diagnosis.

**Note** A review and validation of the Karnofsky performance status scale can be found as a free access article here:

Mor, V., Laliberte, L., Morris, J.N. and Wiemann, M. (1984), The Karnofsky performance status scale: An examination of its reliability and validity in a research setting. Cancer, 53: 2002-2007. https://doi.org/10.1002/1097-0142(19840501)53:9<2002::AID-CNCR2820530933>3.0.CO;2-W

**Note** The original publication and validation of the Lansky performance status scale can be found as a free access article here:

Lansky, S.B., List, M.A., Lansky, L.L., Ritter-Sterr, C. and Miller, D.R. (1987), The measurement of performance in childhood cancer patients. Cancer, 60: 1651-1656. https://doi.org/10.1002/1097-0142(19871001)60:7<1651::AID-CNCR2820600738>3.0.CO;2-J

**Authority Required**

***16358***

Paediatric low grade glioma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have either: (i) stable, (ii) responding disease based on the Response Assessment in Neuro-Oncology (RANO) criteria, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

**Note** Response in the proposed restrictions is assessed using the Response Assessment for Neuro-Oncology (RANO) 2017 criteria:

Wen PY, Chang SM, Van den Bent MJ, Vogelbaum MA, Macdonald DR, Lee EQ. Response Assessment in Neuro-Oncology Clinical Trials. J Clin Oncol. 2017;35(21): 2439-2449. doi:10.1200/JCO.2017.72.7511

### dabrafenib 10 mg dispersible tablet, 2 x 210

| 14773M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *6,814.82 | 25.00 | Tafinlar [NV] |

### dabrafenib 50 mg capsule, 120

| 14778T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *9,668.88 | 25.00 | Tafinlar [NV] |

### dabrafenib 75 mg capsule, 120

| 14754M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 7,267.49 | 25.00 | Tafinlar [NV] |

## ENCORAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***10271***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**

- The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; **OR**
- Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma, **AND**
- Patient must have a WHO performance status of 2 or less.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**encorafenib 50 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11937G | 9 | 3 | 0.00 | *7,277.37 | 25.00 | Braftovi [FB] |

**encorafenib 75 mg capsule, 42**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11938H | 4 | 3 | 0.00 | *7,036.08 | 25.00 | Braftovi [FB] |

## ENCORAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***12487***
Metastatic colorectal cancer
Treatment Phase: Initial treatment
**Clinical criteria:**

- Patient must have BRAF V600 variant positive metastatic colorectal cancer, **AND**
- The treatment must be in combination with cetuximab, **AND**
- Patient must not have received prior treatment with cetuximab for this condition; **OR**
- Patient must not have developed disease progression while receiving cetuximab for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must have failed to respond to at least one other line of systemic therapy, **AND**
- Patient must have a WHO performance status of 2 or less.

**encorafenib 75 mg capsule, 42**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12814K | 3 | 3 | 0.00 | *5,304.39 | 25.00 | Braftovi [FB] |

## ENCORAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***12484***
Metastatic colorectal cancer
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with cetuximab, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**encorafenib 75 mg capsule, 42**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12815L | 3 | 5 | 0.00 | *5,304.39 | 25.00 | Braftovi [FB] |

## ENCORAFENIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17949***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

### encorafenib 50 mg capsule, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11954E NP | 9 | 5 | 0.00 | *7,277.37 | 25.00 | Braftovi [FB] |

### encorafenib 75 mg capsule, 42

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11949X NP | 4 | 5 | 0.00 | *7,036.08 | 25.00 | Braftovi [FB] |

## VEMURAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***10157***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; **OR**
- Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma, **AND**
- Patient must have a WHO performance status of 2 or less.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

### vemurafenib 240 mg tablet, 56

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11076Y | 4 | 3 | 0.00 | *6,860.80 | 25.00 | Zelboraf [RO] |

## VEMURAFENIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17949***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have stable or responding disease.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**vemurafenib 240 mg tablet, 56**

| 11081F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *6,860.80 | 25.00 | Zelboraf [RO] |

### *Anaplastic lymphoma kinase (ALK) inhibitors*

## ALECTINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18901***

Resected non-small cell lung cancer (NSCLC)

Treatment Phase: Adjuvant therapy

**Clinical criteria:**

- Patient must be both: (i) initiating treatment, (ii) untreated with an Anaplastic Lymphoma Kinase-Tyrosine Kinase Inhibitor (ALK-TKI) for non-small cell lung cancer; **OR**
- Patient must be continuing existing PBS-subsidised treatment with this drug; **OR**
- Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) untreated with ALK-TKI at the time this drug was initiated, **AND**
- The condition must be/have been at least one of: (i) node positive, (ii) at least 4 cm in size, **AND**
- The treatment must be for the purpose of adjuvant therapy following surgical resection, **AND**
- The treatment must be commenced within 26 weeks of surgery, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing, **AND**
- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 24 months of combined non-PBS and PBS-subsidised treatment for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**alectinib 150 mg capsule, 4 x 56**

| 15376G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 6,579.20 | 25.00 | Alecensa [RO] |

## ALECTINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18725***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with alectinib as adjuvant therapy in resected non-small cell lung cancer, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Authority Required**

***18726***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this indication (i.e. for stage IIIB/IV NSCLC), **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**alectinib 150 mg capsule, 4 x 56**

| 11226W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 6,579.20 | 25.00 | Alecensa [RO] |

## BRIGATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17870***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**brigatinib 30 mg tablet, 28**

| 11980M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 3 | 0.00 | *6,648.20 | 25.00 | Alunbrig [TK] |

**brigatinib 90 mg tablet, 28**

| 11974F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 6,579.20 | 25.00 | Alunbrig [TK] |

**brigatinib 180 mg tablet, 28**

| 11984R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 6,579.20 | 25.00 | Alunbrig [TK] |

## BRIGATINIB

**Caution** Careful monitoring of patients is required due to risk of developing pulmonary adverse events observed in patients within the first seven days of treatment with this drug. Patients must be instructed to report any new or worsening respiratory symptoms.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15759***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

**brigatinib 90 mg tablet [7] (&) brigatinib 180 mg tablet [21], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11976H | ‡1 | 0 | 0.00 | 6,579.20 | 25.00 | Alunbrig [TK] |

## CERITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**
***17947***
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment
**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Authority Required**
***17870***
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Continuing treatment
**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**ceritinib 150 mg capsule, 3 x 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11056X NP | 1 | 3 | 0.00 | 7,039.69 | 25.00 | Zykadia [NV] |

## CRIZOTINIB

**Note** Special Pricing Arrangements apply.

**Authority Required**
***17802***
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment
**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

**Treatment criteria:**

- Must be treated by a medical practitioner.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.
If the application is submitted through HPOS form upload or mail, it must include:
(a) details of the proposed prescription; and
(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
The following must be documented in the patient's medical records:
(a) evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***17805***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**crizotinib 200 mg capsule, 60**

| 10323H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 6,694.33 | 25.00 | Xalkori [PF] |

**crizotinib 250 mg capsule, 60**

| 10322G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 6,694.33 | 25.00 | Xalkori [PF] |

## CRIZOTINIB

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18004***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing, **AND**
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; **OR**
- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal.

**Treatment criteria:**

- Must be treated by a medical practitioner.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be documented in the patient's medical records:

(a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***17805***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**crizotinib 200 mg capsule, 60**

| 11589Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 6,694.33 | 25.00 | Xalkori [PF] |

**crizotinib 250 mg capsule, 60**

| 11594F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 6,694.33 | 25.00 | Xalkori [PF] |

## LORLATINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17914***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Authority Required**

***18022***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**lorlatinib 25 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12096P NP | 1 | 3 | 0.00 | 6,530.27 | 25.00 | Lorviqua [PF] |

**lorlatinib 100 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12091J NP | 1 | 3 | 0.00 | 6,530.27 | 25.00 | Lorviqua [PF] |

### *Mitogen-activated protein kinase (MEK) inhibitors*

## BINIMETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***10328***
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Initial treatment
**Clinical criteria:**

- Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition.

**binimetinib 15 mg tablet, 84**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11948W | 2 | 3 | 0.00 | *7,349.78 | 25.00 | Mektovi [FB] |

## BINIMETINIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***17917***
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**binimetinib 15 mg tablet, 84**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11961M NP | 2 | 5 | 0.00 | *7,349.78 | 25.00 | Mektovi [FB] |

## COBIMETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***10033***
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Initial treatment
**Clinical criteria:**

- Patient must be receiving PBS subsidised vemurafenib concomitantly for this condition.

**cobimetinib 20 mg tablet, 63**

| 11074W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 7,142.32 | 25.00 | Cotellic [RO] |

## COBIMETINIB

**Note** A patient who has had progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17807***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised vemurafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**cobimetinib 20 mg tablet, 63**

| 11075X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 7,142.32 | 25.00 | Cotellic [RO] |

## SELUMETINIB

**Note** The Karnofsky Performance Score is available at:
https://oncologypro.esmo.org/oncology-in-practice/practice-tools/performance-scales
www.mdcalc.com/calc/3168/karnofsky-performance-status-scale

**Note** The Lansky Performance Score is available at:
www.mdcalc.com/calc/3176/lansky-play-performace-scale-pediatric-functional-status

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15490***

Neurofibromatosis type 1

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have plexiform neurofibroma(s) (PN) that is causing/likely to cause at least one of: (i) significant symptoms/morbidity, (ii) disability, (iii) disfigurement, (iv) impairment of normal body function, **AND**
- Patient must have PN for which complete resection cannot be performed, **AND**
- Patient must have either a: (i) Karnofsky, (ii) Lansky Performance Score of at least 70%.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a specialist physician with expertise in neurofibromatosis, (ii) a medical practitioner in consultation with a specialist physician with expertise in neurofibromatosis if attendance is not possible due to geographic isolation.

**Population criteria:**

- Patient must be aged between 2 to 18 years
- Patient must be able to swallow the whole capsule form of this drug.

At the time of the authority application, medical practitioners must request the appropriate number of packs of appropriate strength(s) to provide sufficient drug, based on the body surface area (BSA) of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised**.**

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

For the purpose of administering this restriction, significant symptoms/morbidity are defined as, but not limited to:

1. head and neck PN that can compromise the airway or great vessels;
2. paraspinal PN that can cause myelopathy;
3. brachial or lumbar plexus PN that can cause nerve compression and loss of function;
4. PN that can result in major deformity or significant disfiguring (e.g. orbital PN);
5. PN of the extremity that can cause limb hypertrophy or loss of function; and
6. painful PN.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***15477***

Neurofibromatosis type 1

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be tolerating treatment, **AND**
- Patient must have achieved either: (i) stabilisation of disease, (ii) adequate response to treatment, if have received at least 12 months of treatment with this drug.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a specialist physician with expertise in neurofibromatosis, (ii) a medical practitioner in consultation with a specialist physician with expertise in neurofibromatosis if attendance is not possible due to geographic isolation.

At the time of the authority application, medical practitioners must request the appropriate number of packs of appropriate strength(s) to provide sufficient drug, based on the body surface area (BSA) of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised**.**

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

For the purpose of administering this restriction, adequate response is defined as:

1. stability or improvement of the initial baseline measurements prior to initiating treatment with this drug;

2. relevant imaging has not shown an increase in tumour size of 20% or more.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***15491***

Neurofibromatosis type 1

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition prior to 1 August 2024; **OR**
- Patient must have previously received treatment with another mitogen-activated protein kinase (MEK) inhibitor for this condition prior to 1 August 2024, **AND**
- Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS-subsidised supply of a MEK inhibitor (including selumetinib) was commenced, the patient: (i) had PN that caused/was likely to cause at least one of: (a) significant symptoms/morbidity, (b) disability, (c) disfigurement, (d) impairment of normal body function; (ii) had PN for which complete PN resection could not be performed either: (a) safely, (b) without causing unacceptable morbidity; (iii) had either a: (a) Karnofsky, (b) Lansky Performance Score of at least 70%; (iv) was aged between 2 to 18 years; (v) was able to swallow the whole capsule form if received non-PBS supply with selumetinib, **AND**
- Patient must be tolerating treatment, **AND**
- Patient must have achieved either: (i) stabilisation of disease, (ii) adequate response to treatment, if have received at least 12 months of treatment.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a specialist physician with expertise in neurofibromatosis, (ii) a medical practitioner in consultation with a specialist physician with expertise in neurofibromatosis if attendance is not possible due to geographic isolation.

At the time of the authority application, medical practitioners must request the appropriate number of packs of appropriate strength(s) to provide sufficient drug, based on the body surface area (BSA) of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised**.**

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

For the purpose of administering this restriction, significant symptoms/morbidity are defined as, but not limited to:
1. head and neck PN that can compromise the airway or great vessels;
2. paraspinal PN that can cause myelopathy;
3. brachial or lumbar plexus PN that can cause nerve compression and loss of function;
4. PN that can result in major deformity or significant disfiguring (e.g. orbital PN);
5. PN of the extremity that can cause limb hypertrophy or loss of function; and
6. painful PN.

For the purpose of administering this restriction, adequate response is defined as:
1. stability or improvement of the initial baseline measurements prior to initiating treatment with this drug;
2. relevant imaging has not shown an increase in tumour size of 20% or more.

The authority application must be made in writing and must include:
(1) details of the proposed prescription; and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**selumetinib 10 mg capsule, 60**

| 14236G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 7,221.36 | 25.00 | Koselugo [XI] |

**selumetinib 25 mg capsule, 60**

| 14287Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 17,707.36 | 25.00 | Koselugo [XI] |

## TRAMETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***10051***
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Initial treatment
**Clinical criteria:**

- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition.

**trametinib 500 microgram tablet, 30**

| 10403M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 3 | 0.00 | *5,529.72 | 25.00 | Mekinist [NV] |

**trametinib 2 mg tablet, 30**

| 10382K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 7,267.49 | 25.00 | Mekinist [NV] |

## TRAMETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***17286***
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
**Clinical criteria:**

- Patient must have/have had a WHO performance status of no greater than 2 at treatment initiation with this drug for this condition, **AND**
- The condition must be positive for a BRAF V600E mutation, **AND**
- Patient must be receiving trametinib and dabrafenib concomitantly for this condition.

**Treatment criteria:**

- Patient must be undergoing initial treatment with this drug; **OR**
- Patient must be undergoing continuing treatment with this drug, with an absence of further disease progression while being treated with this drug; **OR**
- Patient must be undergoing non-PBS-subsidised treatment with this drug for this PBS indication, with an absence of further disease progression since commencing non-PBS-subsidised supply.

**trametinib 500 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15051E | 3 | 5 | 0.00 | *5,529.72 | 25.00 | Mekinist [NV] |

**trametinib 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15057L | 1 | 5 | 0.00 | 7,267.49 | 25.00 | Mekinist [NV] |

## TRAMETINIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17951***

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**trametinib 500 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10385N NP | 3 | 5 | 0.00 | *5,529.72 | 25.00 | Mekinist [NV] |

**trametinib 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10405P NP | 1 | 5 | 0.00 | 7,267.49 | 25.00 | Mekinist [NV] |

## TRAMETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17950***

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must commence within 12 weeks of complete resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Authority Required**

***17915***
Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection, **AND**
- Patient must not have experienced disease recurrence, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**trametinib 500 microgram tablet, 30**

| 11821E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 3 | 0.00 | *5,529.72 | 25.00 | Mekinist [NV] |

**trametinib 2 mg tablet, 30**

| 11819C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 7,267.49 | 25.00 | Mekinist [NV] |

## TRAMETINIB

**Note** Trametinib is available as tablets and oral solution. Caution is advised when consideration is given to changing formulations as the formulations are not bioequivalent. Frequent switching between formulations is discouraged.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**
***16371***
Paediatric high grade glioma
**Clinical criteria:**

- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

**trametinib 50 microgram/mL powder for oral liquid, 90 mL**

| 14742X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 13 | 3 | 0.00 | *7,930.14 | 25.00 | Mekinist [NV] |

**trametinib 500 microgram tablet, 30**

| 14780X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 3 | 0.00 | *7,336.52 | 25.00 | Mekinist [NV] |

**trametinib 2 mg tablet, 30**

| 14774N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 7,267.49 | 25.00 | Mekinist [NV] |

## TRAMETINIB

**Note** Trametinib is available as tablets and oral solution. Caution is advised when consideration is given to changing formulations as the formulations are not bioequivalent. Frequent switching between formulations is discouraged.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**
***16372***
Paediatric low grade glioma
**Clinical criteria:**

- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition.

**trametinib 50 microgram/mL powder for oral liquid, 90 mL**

| 14761X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 13 | 3 | 0.00 | *7,930.14 | 25.00 | Mekinist [NV] |

**trametinib 500 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14779W | 4 | 3 | 0.00 | *7,336.52 | 25.00 | Mekinist [NV] |

**trametinib 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14767F | 1 | 3 | 0.00 | 7,267.49 | 25.00 | Mekinist [NV] |

### *Cyclin-dependent kinase (CDK) inhibitors*

## ABEMACICLIB

**Note** The Nottingham grading system is the histologic grading system developed by Elston and Ellis as a modification of the Scarff-Bloom-Richardson grading system. See the following literature publication for details:

Elston, CW, Ellis, IO. Pathological prognostic factors in breast cancer. The value of histological grade in breast cancer: experience from a large study with long-term follow-up. Histopathology. 1991 Nov;19(5):403-10.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***19282***

Early breast cancer

**Clinical criteria:**

- The treatment must be adjuvant to surgical resection, **AND**
- Patient must have been untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy at the time non-PBS-subsidised or PBS-subsidised treatment was initiated; **OR**
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing a CDK4/6 inhibitor therapy for this condition, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system), **AND**
- The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 2 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression, **AND**
- The treatment must not be in combination with any of the following: (i) olaparib, (ii) pembrolizumab, (iii) ribociclib.

**Treatment criteria:**

- Patient must be undergoing concurrent treatment with endocrine therapy where this drug is being prescribed as a PBS benefit, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

Retain all pathology imaging and investigative test results in the patient's medical records.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**abemaciclib 50 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14116Y NP | 1 | 5 | 0.00 | 4,093.49 | 25.00 | Verzenio [LY] |

**abemaciclib 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14105J NP | 1 | 5 | 0.00 | 4,093.49 | 25.00 | Verzenio [LY] |

**abemaciclib 150 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14134X NP | 1 | 5 | 0.00 | 4,093.49 | 25.00 | Verzenio [LY] |

## ABEMACICLIB

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17774***

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; **OR**
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; **OR**
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Population criteria:**

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**Authority Required**

***17847***

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Population criteria:**

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**abemaciclib 50 mg tablet, 56**

| 11876C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 4,093.49 | 25.00 | Verzenio [LY] |

**abemaciclib 100 mg tablet, 56**

| 11871T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 4,093.49 | 25.00 | Verzenio [LY] |

**abemaciclib 150 mg tablet, 56**

| 11868P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 4,093.49 | 25.00 | Verzenio [LY] |

## PALBOCICLIB

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17851***

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; **OR**
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with a non-steroidal aromatase inhibitor; **OR**
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Population criteria:**

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**Authority Required**

***17906***

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Population criteria:**

- Patient must not be premenopausal.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**palbociclib 75 mg tablet, 21**

| 12818P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,697.38 | 25.00 | Ibrance [PF] |

**palbociclib 100 mg tablet, 21**

| 12819Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,697.38 | 25.00 | Ibrance [PF] |

**palbociclib 125 mg tablet, 21**

| 12822W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,697.38 | 25.00 | Ibrance [PF] |

## RIBOCICLIB

**Caution** QT interval monitoring is required for patients treated with this drug.

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** The Nottingham grading system is the histologic grading system developed by Elston and Ellis as a modification of the Scarff-Bloom-Richardson grading system. See the following literature publication for details:

Elston, CW, Ellis, IO. Pathological prognostic factors in breast cancer. The value of histological grade in breast cancer: experience from a large study with long-term follow-up. Histopathology. 1991 Nov;19(5):403-10.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***19283***

Early breast cancer

**Clinical criteria:**

- The treatment must be adjuvant to surgical resection, **AND**
- Patient must have been untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy at the time non-PBS-subsidised or PBS-subsidised treatment was initiated; **OR**
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing a CDK4/6 inhibitor therapy for this condition, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system), **AND**
- The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 3 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression, **AND**
- The treatment must not be in combination with any of the following: (i) abemaciclib, (ii) olaparib, (iii) pembrolizumab, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets.

**Treatment criteria:**

- Patient must be undergoing concurrent treatment with a non-steroidal aromatase inhibitor where this drug is being prescribed as a PBS benefit, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

Retain all pathology imaging and investigative test results in the patient's medical records.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**ribociclib 200 mg tablet, 21**

| 14851P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 1,742.29 | 25.00 | Kisqali [NV] |

## RIBOCICLIB

**Caution** QT interval monitoring is required for patients treated with this drug.

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** The Nottingham grading system is the histologic grading system developed by Elston and Ellis as a modification of the Scarff-Bloom-Richardson grading system. See the following literature publication for details:

Elston, CW, Ellis, IO. Pathological prognostic factors in breast cancer. The value of histological grade in breast cancer: experience from a large study with long-term follow-up. Histopathology. 1991 Nov;19(5):403-10.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***19280***

Early breast cancer

**Clinical criteria:**

- The treatment must be adjuvant to surgical resection, **AND**
- Patient must have been untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy at the time non-PBS-subsidised or PBS-subsidised treatment was initiated; **OR**
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing a CDK4/6 inhibitor therapy for this condition, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system), **AND**
- The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 3 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression, **AND**
- The treatment must not be in combination with any of the following: (i) abemaciclib, (ii) olaparib, (iii) pembrolizumab.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine, **AND**
- Patient must be undergoing concurrent treatment with a non-steroidal aromatase inhibitor where this drug is being prescribed as a PBS benefit.

Retain all pathology imaging and investigative test results in the patient's medical records.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**ribociclib 200 mg tablet, 42**

| 14863G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,387.18 | 25.00 | Kisqali [NV] |

## RIBOCICLIB

**Caution** QT interval monitoring is required for patients treated with this drug.

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18033***

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; **OR**
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; **OR**
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Population criteria:**

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**Authority Required**

***17853***

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Population criteria:**

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**ribociclib 200 mg tablet, 21**

| 11385F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 1,742.29 | 25.00 | Kisqali [NV] |

## RIBOCICLIB

**Caution** QT interval monitoring is required for patients treated with this drug.

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17774***

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; **OR**
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; **OR**
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Population criteria:**

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**Authority Required**

***17847***

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Population criteria:**

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**ribociclib 200 mg tablet, 63**

| 11386G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,014.59 | 25.00 | Kisqali [NV] |

## RIBOCICLIB

**Caution** QT interval monitoring is required for patients treated with this drug.

**Note** Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

**Note** Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17940***

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; **OR**
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; **OR**
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 42 tablets.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Population criteria:**

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**Authority Required**

***17977***

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**

- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 42 tablets.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Population criteria:**

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

**ribociclib 200 mg tablet, 42**

| 11397W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,387.18 | 25.00 | Kisqali [NV] |

## *Mammalian target of rapamycin (mTOR) kinase inhibitors*

### EVEROLIMUS

**Authority Required**

***4351***

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; **OR**
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

**everolimus 2.5 mg tablet, 30**

| 2818H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 445.61 | 25.00 | Afinitor [NV] |

### EVEROLIMUS

**Authority Required (STREAMLINED)**

***7431***

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; **OR**
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated a response to prior treatment.

**everolimus 2.5 mg tablet, 30**

| 11258M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 445.61 | 25.00 | Afinitor [NV] |

**everolimus 5 mg tablet, 30**

| 11254H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 881.87 | 25.00 | Afinitor [NV] |

**everolimus 10 mg tablet, 30**

| 11267B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,740.04 | 25.00 | Afinitor [NV] |

### EVEROLIMUS

**Authority Required (STREAMLINED)**

***7432***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**everolimus 5 mg tablet, 30**

| 11257L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 881.87 | 25.00 | Afinitor [NV] |

**everolimus 10 mg tablet, 30**

| 11262R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,740.04 | 25.00 | Afinitor [NV] |

## EVEROLIMUS

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17449***

Refractory seizures associated with tuberous sclerosis complex

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a confirmed diagnosis of tuberous sclerosis complex (TSC), **AND**
- Patient must be experiencing a minimum of two partial-onset seizures per week, **AND**
- The condition must have failed to be controlled satisfactorily at stable doses of at least two antiseizure medications, **AND**
- The treatment must be in combination with at least one antiseizure medication, **AND**
- Patient must not be a candidate for curative surgery.

**Population criteria:**

- Patient must be at least 2 years of age.

**everolimus 2 mg dispersible tablet, 30**

| 11591C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 358.28 | 25.00 | Afinitor [NV] |

**everolimus 3 mg dispersible tablet, 30**

| 11599L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 532.73 | 25.00 | Afinitor [NV] |

**everolimus 5 mg dispersible tablet, 30**

| 11592D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 881.65 | 25.00 | Afinitor [NV] |

## EVEROLIMUS

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17539***

Refractory seizures associated with tuberous sclerosis complex

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have maintained a response to the PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with at least one antiseizure medication, **AND**
- Patient must not be a candidate for curative surgery.

**everolimus 2 mg dispersible tablet, 30**

| 11607X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 358.28 | 25.00 | Afinitor [NV] |

**everolimus 3 mg dispersible tablet, 30**

| 11608Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 532.73 | 25.00 | Afinitor [NV] |

**everolimus 5 mg dispersible tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11598K | 1 | 5 | 0.00 | 881.65 | 25.00 | Afinitor [NV] |

## EVEROLIMUS

**Authority Required**

***4351***

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; **OR**
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

**Authority Required**

***4812***

Metastatic (Stage IV) breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole, **AND**
- The treatment must be in combination with exemestane.

**Population criteria:**

- Patient must not be pre-menopausal.

**Note** Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**everolimus 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2819J | 1 | 5 | 0.00 | 881.87 | 25.00 | Afinitor [NV] |

**everolimus 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2985D | 1 | 5 | 0.00 | 1,740.04 | 25.00 | Afinitor [NV] |

## EVEROLIMUS

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***8622***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**everolimus 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10133H | 1 | 2 | 0.00 | 881.87 | 25.00 | Afinitor [NV] |

**everolimus 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10132G | 1 | 2 | 0.00 | 1,740.04 | 25.00 | Afinitor [NV] |

## EVEROLIMUS

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4837***

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have disease progression, **AND**
- The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

**everolimus 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10131F | 1 | 5 | 0.00 | 881.87 | 25.00 | Afinitor [NV] |

**everolimus 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10135K | 1 | 5 | 0.00 | 1,740.04 | 25.00 | Afinitor [NV] |

## EVEROLIMUS

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17677***

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be symptomatic (despite somatostatin analogues); **OR**
- Patient must have disease progression, **AND**
- The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease with any of: (i) sunitinib; (ii) cabozantinib are not eligible to receive PBS-subsidised everolimus for this condition.

Patients who have developed intolerance with any of: (i) sunitinib; (ii) cabozantinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

**everolimus 5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11362B | 1 | 2 | 0.00 | 881.87 | 25.00 | Afinitor [NV] |

**everolimus 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11377T | 1 | 2 | 0.00 | 1,740.04 | 25.00 | Afinitor [NV] |

### *Human epidermal growth factor receptor 2 (HER2) tyrosine kinase inhibitors*

## LAPATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***18383***

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must have received prior therapy with a taxane for at least 3 cycles; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; **OR**

- Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; **OR**
- Patient must have experienced disease progression following treatment with trastuzumab emtansine in whom disease had relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; **OR**
- Patient must have experienced disease relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(i) details (date, unique identifying number/code, or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH); and

(ii) date of last treatment with a taxane and total number of cycles; or

(iii) dates of treatment with trastuzumab and pertuzumab; or

(iv) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab and pertuzumab; or

(v) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

All reports must be documented in the patient's medical records.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**lapatinib 250 mg tablet, 70**

9148L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *2,244.20 | 25.00 | Tykerb [NV] |

## LAPATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***9360***

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- The treatment must be in combination with capecitabine, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The treatment must not exceed a lifetime total of one continuous course.

**lapatinib 250 mg tablet, 70**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11251E | 2 | 2 | 0.00 | *2,244.20 | 25.00 | Tykerb [NV] |

### *Janus-associated kinase (JAK) inhibitors*

## FEDRATINIB

**Caution** Thiamine levels should be assessed as per the approved Therapeutic Goods Administration (TGA) Product Information (PI) prior to receiving treatment and should be closely monitored throughout the treatment period.

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) or the Dynamic International Prognostic Scoring System (DIPSS) or the Age-Adjusted DIPSS.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***18324***

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Authority Required (STREAMLINED)**

***18241***

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Fedratinib 100 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15279E NP | 1 | 5 | 0.00 | 5,882.90 | 25.00 | Inrebic [BQ] |

## FEDRATINIB

**Caution** Thiamine levels should be assessed as per the approved Therapeutic Goods Administration (TGA) Product Information (PI) prior to receiving treatment and should be closely monitored throughout the treatment period.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction twice in a lifetime. Patients reinitiating PBS-subsidised treatment following pregnancy are exempt from this rule.

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) or the Dynamic International Prognostic Scoring System (DIPSS) or the Age-Adjusted DIPSS.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16364***

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythaemia vera myelofibrosis, (iii) post-essential thrombocythaemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

Details of the following must be documented in the patient's medical records:

(a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and

(b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**Authority Required**

***16365***
Intermediate-1 risk myelofibrosis
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythaemia vera myelofibrosis, (iii) post-essential thrombocythaemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy; **OR**
- Patient must have intolerance to prior treatment with a JAK inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

Details of the following must be documented in the patient's medical records:
(a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and
(b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**Fedratinib 100 mg capsule, 120**

| 15278D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 5,882.90 | 25.00 | Inrebic [BQ] |

## MOMELOTINIB

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) or the Dynamic International Prognostic Scoring System (DIPSS) or the Age-Adjusted DIPSS.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***18324***
High risk and intermediate-2 risk myelofibrosis
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Authority Required (STREAMLINED)**
***18241***
Intermediate-1 risk myelofibrosis
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Momelotinib 100 mg tablet, 30**

| 14743Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,882.90 | 25.00 | Omjjara [GK] |

**Momelotinib 150 mg tablet, 30**

| 14744B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,882.90 | 25.00 | Omjjara [GK] |

**Momelotinib 200 mg tablet, 30**

| 14770J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,882.90 | 25.00 | Omjjara [GK] |

## MOMELOTINIB

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) or the Dynamic International Prognostic Scoring System (DIPSS) or the Age-Adjusted DIPSS.
**Note** A patient may only qualify for PBS-subsidised treatment under this restriction twice in a lifetime. Patients reinitiating PBS-subsidised treatment following pregnancy are exempt from this rule.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**

***16363***

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythaemia vera myelofibrosis, (iii) post-essential thrombocythaemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- Patient must have a haemoglobin level of less than 100 g per L prior to commencing treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

Details of the following must be documented in the patient's medical records:

(a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and

(b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**Authority Required**

***16390***

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythaemia vera myelofibrosis, (iii) post-essential thrombocythaemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy; **OR**
- Patient must have intolerance to prior treatment with a JAK inhibitor for this condition, **AND**
- Patient must have a haemoglobin level of less than 100 g per L prior to commencing treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

Details of the following must be documented in the patient's medical records:

(a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and

(b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**Momelotinib 100 mg tablet, 30**

| 14769H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 5,882.90 | 25.00 | Omjjara [GK] |

**Momelotinib 150 mg tablet, 30**

| 14762Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 5,882.90 | 25.00 | Omjjara [GK] |

**Momelotinib 200 mg tablet, 30**

| 14763B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 5,882.90 | 25.00 | Omjjara [GK] |

## RUXOLITINIB

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) or the Dynamic International Prognostic Scoring System (DIPSS) or the Age-Adjusted DIPSS.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***18324***

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Authority Required (STREAMLINED)**

***18241***

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**ruxolitinib 5 mg tablet, 56**

| 10616R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *4,758.12 | 25.00 | Jakavi [NV] |

**ruxolitinib 10 mg tablet, 56**

| 10927D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 4,735.11 | 25.00 | Jakavi [NV] |

## RUXOLITINIB

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) or the Dynamic International Prognostic Scoring System (DIPSS) or the Age-Adjusted DIPSS.

**Note** No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***18324***

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Authority Required (STREAMLINED)**

***18241***

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**ruxolitinib 15 mg tablet, 56**

| 10615Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 4,735.11 | 25.00 | Jakavi [NV] |

**ruxolitinib 20 mg tablet, 56**

| 10617T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 4,735.11 | 25.00 | Jakavi [NV] |

## RUXOLITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***13906***

Moderate to severe chronic graft versus host disease (cGVHD)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have received prior systemic steroid treatment for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment, **AND**

- The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors.

**Treatment criteria:**

- Must be treated by a haematologist; **OR**
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; **OR**
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**
- Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation.

The severity of cGVHD is defined by the *National Institutes of Health* (NIH) criteria (Jagasia et al., 2015):

(a) Moderate cGVHD: at least one organ (not lung) with a score of 2, 3 or more organs involved with a score of 1 in each organ, or lung score of 1

(b) Severe cGVHD: at least 1 organ with a score of 3, or lung score of 2 or 3

Steroid-refractory disease is defined as:

(a) a lack of response or disease progression after administration of a minimum prednisone dose of 1 mg/kg/day for at least 1 week (or equivalent); or

(b) disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent).

Steroid-dependent disease is defined as an increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent).

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

Details of prior steroid use should be documented in the patient's medical records.

A patient must demonstrate a response 24 weeks after initiating treatment with ruxolitinib to be eligible for continuing treatment.

Response is defined as attaining a complete or partial response as defined by the *National Institutes of Health* (NIH) criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.

(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.

The assessment of response must be documented in the patient's medical records.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**Authority Required (STREAMLINED)**

***19191***

Moderate to severe chronic graft versus host disease (cGVHD)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received initial PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have responding disease at 24 weeks compared with baseline, demonstrated by either a: (i) partial response, (ii) complete response, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist medical practitioner.

Response is defined as attaining a complete or partial response as defined by the *National Institutes of Health* (NIH) criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.

(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**ruxolitinib 5 mg tablet, 56**

13241X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 2,433.74 | 25.00 | Jakavi [NV] |

NP

**ruxolitinib 10 mg tablet, 56**

| 13235N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 4,735.11 | 25.00 | Jakavi [NV] |

## RUXOLITINIB

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) or the Dynamic International Prognostic Scoring System (DIPSS) or the Age-Adjusted DIPSS.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction twice in a lifetime. Patients reinitiating PBS-subsidised treatment following pregnancy are exempt from this rule.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16364***

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythaemia vera myelofibrosis, (iii) post-essential thrombocythaemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

Details of the following must be documented in the patient's medical records:

(a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and

(b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**Authority Required**

***16365***

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythaemia vera myelofibrosis, (iii) post-essential thrombocythaemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy; **OR**
- Patient must have intolerance to prior treatment with a JAK inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

Details of the following must be documented in the patient's medical records:

(a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and

(b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**ruxolitinib 5 mg tablet, 56**

| 10614P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *4,758.12 | 25.00 | Jakavi [NV] |

**ruxolitinib 10 mg tablet, 56**

| 10913J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 4,735.11 | 25.00 | Jakavi [NV] |

## RUXOLITINIB

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) or the Dynamic International Prognostic Scoring System (DIPSS) or the Age-Adjusted DIPSS.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction twice in a lifetime. Patients reinitiating PBS-subsidised treatment following pregnancy are exempt from this rule.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16364***

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythaemia vera myelofibrosis, (iii) post-essential thrombocythaemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

Details of the following must be documented in the patient's medical records:

(a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and

(b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**Authority Required**

***16365***

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be either: (i) primary myelofibrosis, (ii) post-polycythaemia vera myelofibrosis, (iii) post-essential thrombocythaemia myelofibrosis, confirmed through a bone marrow biopsy report, **AND**
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy; **OR**
- Patient must have intolerance to prior treatment with a JAK inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised JAK inhibitor therapy for this condition.

Details of the following must be documented in the patient's medical records:

(a) the bone marrow biopsy report confirming diagnosis of myelofibrosis (date, unique identifying number/code or provider number); and

(b) a classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**ruxolitinib 15 mg tablet, 56**

| 10619X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 4,735.11 | 25.00 | Jakavi [NV] |

**ruxolitinib 20 mg tablet, 56**

| 10618W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 4,735.11 | 25.00 | Jakavi [NV] |

## RUXOLITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***19103***

Polycythemia vera

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be resistant to hydroxycarbamide (hydroxyurea); **OR**
- Patient must have an intolerance to hydroxycarbamide (hydroxyurea) of a severity necessitating permanent treatment withdrawal; **OR**
- Patient must have developed a clinically important adverse event/contraindication to hydroxycarbamide (hydroxyurea) as defined in the TGA-approved Product Information necessitating permanent treatment withdrawal, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a medical practitioner.

Hydroxycarbamide (hydroxyurea) resistance is defined as a minimum of 12 consecutive weeks treatment at a dose of at least 1.5 grams/day or at the maximum tolerated that still results in one of the following:

(i) the need to reduce haematocrit levels to below 45% through phlebotomy; or

(ii) a platelet count greater than 400 x $10^9$/L and a white blood cell count greater than 10 x $10^9$/L

If applicable, details of prior systemic treatment with hydroxycarbamide (hydroxyurea) that caused either (i) an intolerance, (ii) an adverse event as listed in the TGA-approved Product Information, or (iii) a contraindication as listed in the TGA-approved Product Information necessitating permanent treatment withdrawal should be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**
***19100***
Polycythemia vera
Treatment Phase: Balance of Initial treatment - up to 48 weeks
**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised treatment for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a medical practitioner.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**
***19146***
Polycythemia vera
Treatment Phase: First continuing treatment
**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised treatment for this condition, **AND**
- Patient must have achieved and maintained a response to treatment with this drug for this condition.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a medical practitioner.

A response to treatment is defined as:
(i) Maintaining a haematocrit level of less than 45% without relying on phlebotomy and which was measured at least 12 weeks after the most recent phlebotomy procedure (if performed to reduce red blood cell levels); or
(ii) Ability to demonstrate or maintain a normal platelet count of less than or equal to 400 x $10^9$/L; or
(iii) The absence of palpable splenomegaly.
The following must be documented in the patient's medical records:
(a) details (dates, unique identifying number/code, or provider number) of the pathology report confirming the patient has achieved and maintained a response within 48 weeks of treatment initiation; or
(b) confirmation that the patient does not have palpable splenomegaly.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**
***19104***
Polycythemia vera
Treatment Phase: Subsequent continuing treatment
**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have achieved and maintained a response to treatment with this drug for this condition.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ruxolitinib 5 mg tablet, 56**

| 14990Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 2,433.74 | 25.00 | Jakavi [NV] |

**ruxolitinib 10 mg tablet, 56**

| 14991B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 4,735.11 | 25.00 | Jakavi [NV] |

**ruxolitinib 15 mg tablet, 56**

| 15014F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 4,735.11 | 25.00 | Jakavi [NV] |

**ruxolitinib 20 mg tablet, 56**

| 15002N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 4,735.11 | 25.00 | Jakavi [NV] |

## *Vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitors*

### AXITINIB

**Authority Required (STREAMLINED)**

***7433***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**axitinib 1 mg tablet, 28**

| 10539Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *1,005.64 | 25.00 | Inlyta [PF] |

**axitinib 5 mg tablet, 28**

| 10556N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *4,794.94 | 25.00 | Inlyta [PF] |

### AXITINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***8588***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**axitinib 1 mg tablet, 28**

| 10572K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *1,005.64 | 25.00 | Inlyta [PF] |

**axitinib 5 mg tablet, 28**

| 10540R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *4,794.94 | 25.00 | Inlyta [PF] |

## FRUQUINTINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***18516***

Metastatic colorectal cancer

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- Patient must have/had a WHO performance status of 1 or less, prior to initiation of treatment with this drug for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication; **OR**
- Patient must be each of: (i) currently receiving non-PBS-subsidised supply for this drug for this PBS indication, (ii) untreated with this drug at the time that non-PBS-subsidised supply was commenced, (iii) free of disease progression since commencing non-PBS-subsidised supply, **AND**
- Patient must have been previously treated with or not considered a candidate for treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-vascular endothelial growth factor (anti-VEGF) agent and an anti-epidermal growth factor receptor (anti-EGFR) agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The patient's WHO performance status must be documented in the patient's medical records at the time the treatment is initiated.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction.

**Authority Required (STREAMLINED)**

***18520***

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition.

**fruquintinib 1 mg capsule, 21**

| 15336E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 5 | 0.00 | *5,582.88 | 25.00 | Fruzaqla [TK] |

**fruquintinib 5 mg capsule, 21**

| 15344N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 6,859.26 | 25.00 | Fruzaqla [TK] |

### *Bruton's tyrosine kinase (BTK) inhibitors*

## ACALABRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17898***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Treatment of relapsed/refractory disease

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression, **AND**
- Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); **OR**
- Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**acalabrutinib 100 mg tablet, 56**

| 13318Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 7,159.52 | 25.00 | CALQUENCE [AP] |

## ACALABRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17991***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First line drug treatment of this indication - as monotherapy

**Clinical criteria:**

- The condition must be untreated with drug treatment at the time of the first dose of this drug; **OR**
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; **OR**
- Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**acalabrutinib 100 mg tablet, 56**

| 13792X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 7,159.52 | 25.00 | CALQUENCE [AP] |

## ACALABRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18686***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First line drug treatment of this indication - in combination with obinutuzumab

**Clinical criteria:**

- The condition must be untreated with drug treatment at the time of the first dose of this drug; **OR**
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be initiated as a monotherapy for 1 Cycle with treatment in combination with obinutuzumab from Cycle 2 to 7 (refer to Product Information for timing of obinutuzumab and acalabrutinib doses) after which treatment must be monotherapy, **AND**
- The treatment must not be in combination with venetoclax.

**Treatment criteria:**

- Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; **OR**
- Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**acalabrutinib 100 mg tablet, 56**

| 13810W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 6 | 0.00 | 7,159.52 | 25.00 | CALQUENCE [AP] |

## ACALABRUTINIB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction twice in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18706***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment (treatment cycles 3 to 14 inclusive) of first-line therapy - in combination with venetoclax

**Clinical criteria:**

- Patient must have previously received this drug as their most recent course of PBS-subsidised treatment for this condition, **AND**
- The treatment must not exceed 14 cycles in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first, **AND**
- The treatment must be in combination with venetoclax, **AND**
- The treatment must not be in combination with obinutuzumab.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**acalabrutinib 100 mg tablet, 56**

| 15354D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 7,159.52 | 25.00 | CALQUENCE [AP] |

## ACALABRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**
***18684***
Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)
Treatment Phase: Grandfather arrangements - Transitioning from non-PBS to PBS-subsidised supply in first-line therapy
**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2026, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The condition must have been untreated with drug treatment at the time of the first dose of this drug; **OR**
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line treatment of CLL/SLL prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be in combination with venetoclax as continuing treatment for this condition (treatment cycles 3 to 14 inclusive); **OR**
- The treatment must be as monotherapy for initial treatment of this condition (treatment cycles 1 to 2 inclusive), **AND**
- The treatment must not be in combination with obinutuzumab, **AND**
- The treatment must not exceed 14 cycles in total with this drug, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first.

A patient may qualify for PBS-subsidised treatment under this restriction once only.
For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the next relevant treatment phase.
**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**acalabrutinib 100 mg tablet, 56**

15356F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 7,159.52 | 25.00 | CALQUENCE [AP] |

## ACALABRUTINIB

**Note** For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**
***17930***
Mantle cell lymphoma
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; **OR**
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Authority Required**
***17931***
Mantle cell lymphoma
Treatment Phase: Continuing treatment
**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**acalabrutinib 100 mg tablet, 56**

| 13325H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 7,159.52 | 25.00 | CALQUENCE [AP] |

## ACALABRUTINIB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18615***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment (treatment cycles 1 to 2 inclusive) in first-line therapy

**Clinical criteria:**

- The condition must be untreated with drug treatment at the time of the first dose of this drug; **OR**
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be initiated as monotherapy, with the intention of use in combination with venetoclax from cycle 3 to 14, **AND**
- The treatment must not be in combination with obinutuzumab.

**acalabrutinib 100 mg tablet, 56**

| 15360K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 7,159.52 | 25.00 | CALQUENCE [AP] |

## IBRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17898***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Treatment of relapsed/refractory disease

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression, **AND**
- Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); **OR**
- Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent, **AND**
- Must be treated by a medical practitioner; **OR**

- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**ibrutinib 140 mg capsule, 90**

| 11213E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 8,079.74 | 25.00 | Imbruvica [JC] |

**ibrutinib 280 mg tablet, 30**

| 14074R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,430.62 | 25.00 | Imbruvica [JC] |

**ibrutinib 420 mg tablet, 30**

| 14085H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 8,079.74 | 25.00 | Imbruvica [JC] |

## IBRUTINIB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17900***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Second and final continuing treatment (treatment cycles 10 to 15 inclusive) of first-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with venetoclax (refer to Product Information for timing of ibrutinib and venetoclax doses), **AND**
- The treatment must cease upon disease progression; **OR**
- The treatment must cease upon completion of 15 cycles of treatment with this drug for this condition, whichever comes first.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

There are more ibrutinib capsules (or tablets) in a pack than is required for the completion of a treatment cycle. The patient must not discard any remaining capsules (or tablets) after the completion of any treatment cycle as these capsules (or tablets) will be required for the doses in the final treatment cycle (i.e. treatment cycle 15).

**ibrutinib 140 mg capsule, 90**

| 14596F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 4 | 0.00 | 8,079.74 | 25.00 | Imbruvica [JC] |

**ibrutinib 280 mg tablet, 30**

| 14612C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 4 | 0.00 | 5,430.62 | 25.00 | Imbruvica [JC] |

**ibrutinib 420 mg tablet, 30**

| 14621M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 4 | 0.00 | 8,079.74 | 25.00 | Imbruvica [JC] |

## IBRUTINIB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17838***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First continuing treatment (treatment cycles 4 to 9 inclusive) of first-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must be in combination with venetoclax (refer to Product Information for timing of ibrutinib and venetoclax doses), **AND**
- The treatment must cease upon disease progression.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

There are more ibrutinib capsules (or tablets) in a pack than is required for the completion of a treatment cycle. The patient must not discard any remaining capsules (or tablets) after the completion of any treatment cycle as these capsules (or tablets) will be required for the doses in the final treatment cycle (i.e. treatment cycle 15).

**ibrutinib 140 mg capsule, 90**

| 14604P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 8,079.74 | 25.00 | Imbruvica [JC] |

**ibrutinib 280 mg tablet, 30**

| 14620L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,430.62 | 25.00 | Imbruvica [JC] |

**ibrutinib 420 mg tablet, 30**

| 14603N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 8,079.74 | 25.00 | Imbruvica [JC] |

## IBRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15864***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment in first-line therapy (treatment cycles 1 to 3 inclusive)

**Clinical criteria:**

- The condition must be untreated with drug treatment at the time of the first dose of this drug; **OR**
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be in combination with venetoclax (refer to Product Information for timing of ibrutinib and venetoclax doses).

There are more ibrutinib capsules (or tablets) in a pack than is required for the completion of a treatment cycle. The patient must not discard any remaining capsules (or tablets) after the completion of any treatment cycle as these capsules (or tablets) will be required for the doses in the final treatment cycle (i.e. treatment cycle 15).

**ibrutinib 140 mg capsule, 90**

| 14597G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 8,079.74 | 25.00 | Imbruvica [JC] |

**ibrutinib 280 mg tablet, 30**

| 14580J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 5,430.62 | 25.00 | Imbruvica [JC] |

**ibrutinib 420 mg tablet, 30**

| 14598H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 8,079.74 | 25.00 | Imbruvica [JC] |

## IBRUTINIB

**Note** For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17930***

Mantle cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; **OR**
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Authority Required**

***17931***

Mantle cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**ibrutinib 140 mg capsule, 120**

| 11419B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 10,721.09 | 25.00 | Imbruvica [JC] |

**ibrutinib 280 mg tablet, 30**

| 14079B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,430.62 | 25.00 | Imbruvica [JC] |

**ibrutinib 420 mg tablet, 30**

| 14075T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 8,079.74 | 25.00 | Imbruvica [JC] |

**ibrutinib 560 mg tablet, 30**

| 14086J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 10,721.09 | 25.00 | Imbruvica [JC] |

## ZANUBRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17898***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Treatment of relapsed/refractory disease

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression, **AND**
- Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); **OR**
- Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**zanubrutinib 80 mg capsule, 120**

| 13616P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 8,057.72 | 25.00 | Brukinsa [IE] |

## ZANUBRUTINIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17927***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First line drug treatment of this indication

**Clinical criteria:**

- The condition must be untreated with drug treatment at the time of the first dose of this drug; **OR**
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; **OR**
- Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**zanubrutinib 80 mg capsule, 120**

| 13628G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 8,057.72 | 25.00 | Brukinsa [IE] |

## ZANUBRUTINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17961***

Waldenstrom macroglobulinaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior chemo-immunotherapy; **OR**
- Patient must be unsuitable for treatment with chemo-immunotherapy, defined by a Cumulative Illness Rating Scale of 6 or greater, if untreated (i.e. treatment-naive) for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- Patient must be untreated with a Bruton's tyrosine kinase inhibitor for this condition; **OR**
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Authority Required**

***18007***

Waldenstrom macroglobulinaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

### zanubrutinib 80 mg capsule, 120

| 13041J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 8,057.72 | 25.00 | Brukinsa [IE] |

## ZANUBRUTINIB

**Note** For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17930***

Mantle cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; **OR**
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Authority Required**

***17931***

Mantle cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**zanubrutinib 80 mg capsule, 120**

| 12891L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 8,057.72 | 25.00 | Brukinsa [IE] |

## *Phosphatidylinositol-3-kinase (Pi3K) inhibitors*

### IDELALISIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17893***

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**idelalisib 100 mg tablet, 60**

| 12813J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,188.36 | 25.00 | Zydelig [GI] |

**idelalisib 150 mg tablet, 60**

| 12812H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,188.36 | 25.00 | Zydelig [GI] |

### IDELALISIB

**Note** Special Pricing Arrangements apply.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***12490***

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be refractory to a prior therapy with rituximab within 6 months after completion of treatment with rituximab, **AND**
- The condition must be refractory to a prior therapy with an alkylating agent within 6 months after completion of treatment with an alkylating agent, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The condition is considered refractory to a prior therapy when the patient experiences less than a partial response or progression of disease within 6 months after completion of the prior therapy.

The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.

The date of completion of prior therapies with rituximab and an alkylating agent must be documented in the patient's medical records.

**idelalisib 100 mg tablet, 60**

| 11171Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 5,188.36 | 25.00 | Zydelig [GI] |

**idelalisib 150 mg tablet, 60**

| 11165P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 5,188.36 | 25.00 | Zydelig [GI] |

### IDELALISIB

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18008***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be confirmed Chronic lymphocytic leukaemia (CLL) prior to initiation of treatment; **OR**
- The condition must be confirmed Small lymphocytic lymphoma (SLL) prior to initiation of treatment, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab for up to a maximum of 8 doses under this restriction, followed by monotherapy for this condition, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The condition must be CD20 positive, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Authority Required**

***18029***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for Chronic lymphocytic leukaemia; **OR**
- Patient must have previously received PBS-subsidised treatment with this drug for Small lymphocytic leukaemia, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**idelalisib 100 mg tablet, 60**

| 11170X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,188.36 | 25.00 | Zydelig [GI] |

**idelalisib 150 mg tablet, 60**

| 11162L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 5,188.36 | 25.00 | Zydelig [GI] |

## *Fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitors*

### FUTIBATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***18828***

Locally advanced or metastatic cholangiocarcinoma

**Clinical criteria:**

- Patient must have evidence of a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement at treatment initiation, **AND**
- Patient must have/have had received at least one line of systemic therapy prior to treatment initiation, **AND**
- Patient must have/have had a World Health Organisation (WHO) performance status of no greater than 1 at treatment initiation with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**Futibatinib 4 mg tablet, 35**

15401N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 5 | 0.00 | *16,717.28 | 25.00 | Lytgobi [TJ] |

### *Cellular-mesenchymal-epithelial transition factor (c-MET) kinase inhibitors*

## TEPOTINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***13434***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of MET exon 14 skipping alterations in tumour material.

**Authority Required (STREAMLINED)**

***13441***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**tepotinib 225 mg tablet, 60**

13171F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 9,253.40 | 25.00 | Tepmetko [SG] |

### *Other protein kinase inhibitors*

## CABOZANTINIB

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17636***

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) or extra-pancreatic neuroendocrine tumour (epNET)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this drug more than once per lifetime.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Patients who develop disease progression while receiving PBS-subsidised treatment with cabozantinib for this condition are not eligible to receive subsequent PBS-subsidised treatment with any of: (i) sunitinib, (ii) everolimus.

Patients who develop intolerance while receiving PBS-subsidised treatment with cabozantinib are eligible to receive subsequent PBS-subsidised treatment with any of: (i) sunitinib, (ii) everolimus.

**cabozantinib 20 mg tablet, 30**

15130H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

**cabozantinib 40 mg tablet, 30**

15114L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

**cabozantinib 60 mg tablet, 30**

15115M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

## CABOZANTINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17611***

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) or extra-pancreatic neuroendocrine tumour (epNET)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have progressive disease according to Response Evaluation Criteria in Solid Tumours (RECIST) following at least one prior systemic therapy other than a somatostatin analogue for this indication prior to initiating treatment with this drug, **AND**
- Patient must have had a WHO performance status score of no greater than 2 at treatment initiation with this drug.

**Treatment criteria:**

- Patient must not be undergoing treatment with this drug more than once per lifetime.

Patients who develop disease progression while receiving PBS-subsidised treatment with cabozantinib for this condition are not eligible to receive subsequent PBS-subsidised treatment with any of: (i) sunitinib, (ii) everolimus.

Patients who develop intolerance while receiving PBS-subsidised treatment with cabozantinib are eligible to receive subsequent PBS-subsidised treatment with any of: (i) sunitinib, (ii) everolimus.

Disease progression must be documented in the patient's medical records.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**cabozantinib 20 mg tablet, 30**

| 15124B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

**cabozantinib 40 mg tablet, 30**

| 15129G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

**cabozantinib 60 mg tablet, 30**

| 15123Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

## CABOZANTINIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***15774***

Stage IV renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be each of: (i) classified as having an intermediate to poor survival risk score according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), (ii) untreated with a tyrosine kinase inhibitor; **OR**
- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) despite treatment with a tyrosine kinase inhibitor, irrespective of the current IMDC survival risk score, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug for the first time at the time of the first PBS prescription.

**Note** *A* prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.

One point is assigned for each of:

(i) a time of diagnosis to systemic therapy of less than 1 year (ii) a Karnofsky Performance Status of less than 80% (iii) a haemoglobin less than the lower limit of normal (iv) a corrected calcium level greater than the upper limit of normal (v) a neutrophil count greater than the upper limit of normal (vi) a platelet count greater than the upper limit of normal

Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.

Favourable IMDC risk is a score of 0.

Intermediate IMDC risk is a score of 1 to 2.

Poor IMDC risk is a score of 3 to 6.

Document any IMDC risk score assessment in the patient's medical records.

**cabozantinib 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11371L | 1 | 2 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

**cabozantinib 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11369J | 1 | 2 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

**cabozantinib 60 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11360X | 1 | 2 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

## CABOZANTINIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17794***

Stage IV renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**cabozantinib 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11374P NP | 1 | 5 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

**cabozantinib 40 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11368H NP | 1 | 5 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

**cabozantinib 60 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11367G NP | 1 | 5 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

## CABOZANTINIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17791***

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine; **OR**
- Patient must be deemed ineligible for treatment with radioactive iodine, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**cabozantinib 20 mg tablet, 30**

| 14297L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

**cabozantinib 40 mg tablet, 30**

| 14254F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

**cabozantinib 60 mg tablet, 30**

| 14237H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

## CABOZANTINIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** Vascular endothelial growth factor (VEGF)-targeted tyrosine kinase inhibitor's (TKI) include: lenvatinib.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***15454***

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine; **OR**
- Patient must be deemed ineligible for treatment with radioactive iodine, **AND**
- Patient must have progressive disease according to Response Evaluation Criteria in Solid Tumours (RECIST) whilst on treatment with a vascular endothelial growth factor (VEGF)-targeted tyrosine kinase inhibitor (TKI) for this indication; **OR**
- Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to prior VEGF-targeted TKI therapy, **AND**
- Patient must have a WHO performance status of no higher than 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have thyroid stimulating hormone adequately suppressed.

Radioactive iodine refractory is defined as:

(i) a lesion without iodine uptake on a radioactive iodine (RAI) scan; or

(ii) having received a cumulative RAI dose of greater than or equal to 600 mCi; or

(iii) progression within 12 months of a single RAI treatment; or

(iv) progression after two RAI treatments administered within 12 months of each other.

**cabozantinib 20 mg tablet, 30**

| 14265T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

**cabozantinib 40 mg tablet, 30**

| 14246T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

**cabozantinib 60 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14224P | 1 | 2 | 0.00 | 9,628.56 | 25.00 | Cabometyx [IS] |

## CAPIVASERTIB

**Note** AKT pathway testing is recommended (where possible) for PIK3CA, AKT1 and PTEN gene variants.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17573***

Locally advanced or metastatic breast cancer

**Clinical criteria:**

- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be estrogen receptor positive, **AND**
- The treatment must be in combination with fulvestrant, **AND**
- The treatment must be following progression on at least one endocrine-based regimen in the metastatic setting; **OR**
- The treatment must be following recurrence on or within 12 months of completing endocrine-based adjuvant therapy.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription:

1) Evidence of HER2 negative status (evidence obtained in relation to past PBS treatment is acceptable).

2) Evidence of HR status.

**capivasertib 160 mg tablet, 64**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15049C | 1 | 5 | 0.00 | 8,697.30 | 25.00 | Truqap [AP] |

**capivasertib 200 mg tablet, 64**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15059N | 1 | 5 | 0.00 | 8,697.30 | 25.00 | Truqap [AP] |

## ENTRECTINIB

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15776***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing, **AND**
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; **OR**
- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be documented in the patient's medical records:

(a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***13186***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**entrectinib 200 mg capsule, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12092K | 1 | 3 | 0.00 | 7,039.69 | 25.00 | Rozlytrek [RO] |

## GILTERITINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18014***

Relapsed or refractory Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not be for maintenance therapy post-transplant.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, following a response to gilteritinib, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

(a) Leukaemic cells in the CSF; or

(b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or

(c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or

(d) Extramedullary leukaemia.

**gilteritinib 40 mg tablet, 84**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13094E NP | 1 | 4 | 0.00 | 25,315.36 | 25.00 | Xospata [LL] |

## GILTERITINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15526***

Relapsed or refractory Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- The condition must be internal tandem duplication (ITD) and/or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 prior to treatment initiation, **AND**
- The treatment must not be for maintenance therapy post-transplant.

The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.

**gilteritinib 40 mg tablet, 84**

| 13093D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 25,315.36 | 25.00 | Xospata [LL] |

## LAROTRECTINIB

**Note** For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***15781***

Solid tumours with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing for solid tumours (of any type) with confirmed NTRK gene fusion where treatment with this drug is/was initiated in a child; **OR**
- Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing for solid tumours (of certain specified types) with confirmed NTRK gene fusion which either includes: (i) mammary analogue secretory carcinoma of the salivary gland, (ii) secretory breast carcinoma.

**Clinical criteria:**

- The treatment must cease to be a PBS benefit upon radiographic progression, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Where radiographic progression is observed, mark any remaining repeat prescriptions with the word 'cancelled'.

**larotrectinib 20 mg/mL oral liquid, 2 x 50 mL**

| 13289K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 3,498.36 | 25.00 | Vitrakvi [BN] |

**larotrectinib 25 mg capsule, 56**

| 13027P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 2,656.86 | 25.00 | Vitrakvi [BN] |

**larotrectinib 100 mg capsule, 56**

| 13043L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 10,230.36 | 25.00 | Vitrakvi [BN] |

## LAROTRECTINIB

**Note** For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**

***15467***

Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date, **AND**
- The condition must be non-small cell lung cancer confirmed through a pathology report from an Approved Pathology Authority (of any date); **OR**
- The condition must be soft tissue sarcoma confirmed through a pathology report from an Approved Pathology Authority (of any date); **OR**
- The condition must be confirmed through a pathology report from an Approved Pathology Authority (of any date) as either: (i) glioma, (ii) glioneuronal tumour, (iii) glioblastoma, **AND**
- The condition must be metastatic disease; **OR**
- The condition must be both: (i) locally advanced, (ii) unresectable; **OR**
- The condition must be locally advanced where surgical resection is likely to result in severe morbidity, **AND**
- Patient must have received prior systemic treatment for this disease; **OR**
- Patient must have a condition that predisposes them to an unacceptable risk of intolerance to other systemic therapies, **AND**
- The treatment must be the sole PBS-subsidised anti-cancer therapy for this condition, **AND**
- Patient must not receive more than 3 months of treatment under this restriction.

**Treatment criteria:**

- Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.

(b) details of the pathology report establishing the carcinoma type (non-small cell lung cancer, soft tissue sarcoma or either glioma/ glioneuronal tumour/ glioblastoma) being treated, if different to the pathology report provided to substantiate the NTRK gene fusion.

(c) details of prior systemic treatment for this disease or details of the condition that predisposes the patient to an unacceptable risk of intolerance to other systemic therapies.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### larotrectinib 20 mg/mL oral liquid, 2 x 50 mL

| 14230Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 3,498.36 | 25.00 | Vitrakvi [BN] |

### larotrectinib 25 mg capsule, 56

| 14257J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 2,656.86 | 25.00 | Vitrakvi [BN] |

### larotrectinib 100 mg capsule, 56

| 14300P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 10,230.36 | 25.00 | Vitrakvi [BN] |

## LAROTRECTINIB

**Note** For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15509***

Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be either: (i) non-small cell lung cancer, (ii) soft tissue sarcoma, (iii) glioma, (iv), glioneuronal tumour, (v) glioblastoma, **AND**
- The treatment must cease to be a PBS benefit upon radiographic progression, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

**Population criteria:**

- Patient must be at least 18 years of age.

Where radiographic progression is observed, mark any remaining repeat prescriptions with the word 'cancelled'.

**larotrectinib 20 mg/mL oral liquid, 2 x 50 mL**

| 14256H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 3,498.36 | 25.00 | Vitrakvi [BN] |

**larotrectinib 25 mg capsule, 56**

| 14258K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 2,656.86 | 25.00 | Vitrakvi [BN] |

**larotrectinib 100 mg capsule, 56**

| 14282Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 10,230.36 | 25.00 | Vitrakvi [BN] |

## LAROTRECTINIB

**Note** For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18384***

Solid tumours (of any type) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion where treatment with this drug is/was initiated in a child

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date, **AND**
- The condition must be metastatic disease; **OR**
- The condition must be both: (i) locally advanced, (ii) unresectable; **OR**
- The condition must be both: (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.

**Population criteria:**

- Patient must be/have been under 18 years of age (i.e. prior to their 18th birthday) at treatment initiation with this drug.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority Required**

***18385***

Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date, **AND**
- The condition must be a mammary analogue secretory carcinoma of the salivary gland confirmed through a pathology report from an Approved Pathology Authority (of any date); **OR**
- The condition must be a secretory breast carcinoma confirmed through a pathology report from an Approved Pathology Authority (of any date), **AND**
- The condition must be metastatic disease; **OR**
- The condition must be both: (i) locally advanced, (ii) unresectable; **OR**
- The condition must be both: (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.

(b) details of the pathology report establishing the carcinoma type (salivary gland/secretory breast carcinoma) being treated, if different to the pathology report provided to substantiate the NTRK gene fusion.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### larotrectinib 20 mg/mL oral liquid, 2 x 50 mL

| 13281B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 3,498.36 | 25.00 | Vitrakvi [BN] |

### larotrectinib 25 mg capsule, 56

| 13029R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 2,656.86 | 25.00 | Vitrakvi [BN] |

### larotrectinib 100 mg capsule, 56

| 13031W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 10,230.36 | 25.00 | Vitrakvi [BN] |

## LENVATINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17864***

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have symptomatic progressive disease prior to treatment; **OR**
- Patient must have progressive disease at critical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures, **AND**
- Patient must have thyroid stimulating hormone adequately suppressed, **AND**
- Patient must be one in whom surgery is inappropriate, **AND**
- Patient must not be a candidate for radiotherapy with curative intent, **AND**
- Patient must have a WHO performance status of 2 or less.

**Treatment criteria:**

- Must be treated by a medical practitioner.

Radioactive iodine refractory is defined as:
(i) a lesion without iodine uptake on a radioactive iodine (RAI) scan; or
(ii) having received a cumulative RAI dose of greater than or equal to 600 mCi; or
(iii) progression within 12 months of a single RAI treatment; or
(iv) progression after two RAI treatments administered within 12 months of each other.

**Authority Required (STREAMLINED)**

***17865***

Locally advanced or metastatic differentiated thyroid cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be refractory to radioactive iodine, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**lenvatinib 4 mg capsule, 30**

| 10952K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 2,172.36 | 25.00 | Lenvima [EI] |

**lenvatinib 10 mg capsule, 30**

| 10965D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *4,235.36 | 25.00 | Lenvima [EI] |

## LENVATINIB

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17793***

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be suitable for transarterial chemoembolisation, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A, **AND**
- The condition must be untreated with systemic therapy; **OR**
- Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to any of the following: (i) a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI), (ii) atezolizumab/bevacizumab combination therapy, (iii) durvalumab/tremelimumab combination therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner.

**Authority Required (STREAMLINED)**

***18018***

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

### lenvatinib 4 mg capsule, 30

| 11638M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 2 | 0.00 | *6,298.35 | 25.00 | Lenvima [EI] |

## LENVATINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17786***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records, **AND**
- The condition must be untreated, **AND**
- Patient must have a WHO performance status of 2 or less.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; **OR**
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records, **AND**
- Must be treated by a medical practitioner.

**Note** *A* prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.

One point is assigned for each of:

(i) a time of diagnosis to systemic therapy of less than 1 year (ii) a Karnofsky Performance Status of less than 80% (iii) a haemoglobin less than the lower limit of normal (iv) a corrected calcium level greater than the upper limit of normal (v) a neutrophil count greater than the upper limit of normal (vi) a platelet count greater than the upper limit of normal

Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.

Favourable IMDC risk is a score of 0.

Intermediate IMDC risk is a score of 1 to 2.

Poor IMDC risk is a score of 3 to 6.

Document any IMDC risk score assessment in the patient's medical records.

**Authority Required (STREAMLINED)**

***17860***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; **OR**
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; **OR**
- Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, **AND**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

In a patient who has experienced an intolerance to pembrolizumab, details of intolerance must be documented in the patient's medical record.

**lenvatinib 4 mg capsule, 30**

| 13252L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *4,235.36 | 25.00 | Lenvima [EI] |

## LENVATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17786***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records, **AND**
- The condition must be untreated, **AND**
- Patient must have a WHO performance status of 2 or less.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; **OR**
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records, **AND**
- Must be treated by a medical practitioner.

**Note** *A* prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.

One point is assigned for each of:

(i) a time of diagnosis to systemic therapy of less than 1 year (ii) a Karnofsky Performance Status of less than 80% (iii) a haemoglobin less than the lower limit of normal (iv) a corrected calcium level greater than the upper limit of normal (v) a neutrophil count greater than the upper limit of normal (vi) a platelet count greater than the upper limit of normal

Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.

Favourable IMDC risk is a score of 0.

Intermediate IMDC risk is a score of 1 to 2.

Poor IMDC risk is a score of 3 to 6.

Document any IMDC risk score assessment in the patient's medical records.

**Authority Required (STREAMLINED)**

***17860***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; **OR**
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; **OR**
- Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

In a patient who has experienced an intolerance to pembrolizumab, details of intolerance must be documented in the patient's medical record.

**lenvatinib 10 mg capsule, 30**

| 13253M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *4,235.36 | 25.00 | Lenvima [EI] |

## LENVATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***17943***
Advanced, metastatic or recurrent endometrial carcinoma
Treatment Phase: Initial treatment
**Clinical criteria:**

- Patient must have received prior treatment with platinum-based chemotherapy, **AND**
- The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; **OR**
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records, **AND**
- Must be treated by a medical practitioner.

**Authority Required (STREAMLINED)**
***18017***
Advanced, metastatic or recurrent endometrial carcinoma
Treatment Phase: Continuing treatment
**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; **OR**
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; **OR**
- Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**lenvatinib 4 mg capsule, 30**

| 13290L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *4,235.36 | 25.00 | Lenvima [EI] |

**lenvatinib 10 mg capsule, 30**

| 13283D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *4,235.36 | 25.00 | Lenvima [EI] |

## NINTEDANIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**
***17372***
Progressive fibrosing Interstitial lung disease
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must be diagnosed through a multidisciplinary team, **AND**
- The condition must have chest imaging through high resolution computed tomography (HRCT) that is no older than 12 months, to support the diagnosis of the PBS indication, **AND**
- The condition must display, through HRCT, an affected area of no less than 10% (after rounding to the nearest multiple of 5), **AND**

- Patient must have a current (no older than 2 years) forced vital capacity (FVC) measurement of no less than 45% predicted, adjusted for each of: (i) age, (ii) gender, (iii) height, **AND**
- The condition must be of a progressive nature, observed by, in the 2 years leading up to this authority application, any of: (i) a worsening in relative FVC% predicted measurement of no less than 10%, (ii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with worsening of respiratory symptoms, (iii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with increases in fibrosis observed on HRCT; document at least one of (i) to (iii) in the patient's medical records, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must not have had an acute respiratory infection at the time of FVC measurement, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin that is both: (i) at least 30% predicted, (ii) no greater than 80% predicted, **AND**
- The condition must not be interstitial lung disease due to idiopathic pulmonary fibrosis (apply under the correct PBS listing if it is), **AND**
- The condition must not be due to reversible causes (e.g. drug toxicity).

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.

**Note** Interstitial lung disease includes, but is not limited to:

(i) connective tissue associated interstitial lung disease; (ii) chronic fibrosing hypersensitivity pneumonitis; (iii) idiopathic non-specific interstitial pneumonia; (iv) pulmonary sarcoidosis.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17393***

Progressive fibrosing Interstitial lung disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**nintedanib 100 mg capsule, 60**

| 12967L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 1,680.56 | 25.00 | Ofev [BY] |

**nintedanib 150 mg capsule, 60**

| 12953R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,269.59 | 25.00 | Ofev [BY] |

## NINTEDANIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17320***

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

**Clinical criteria:**

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must not have had an acute respiratory infection at the time of FVC measurement, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***17277***

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or recommencement of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***17329***

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**nintedanib 100 mg capsule, 60**

| 11100F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 1,680.56 | 25.00 | Ofev [BY] |

**nintedanib 150 mg capsule, 60**

| 11106M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,269.59 | 25.00 | Ofev [BY] |

## PAZOPANIB

**Authority Required (STREAMLINED)**

***11939***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**pazopanib 200 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2232L | 1 | 5 | 0.00 | 445.11 | 25.00 | [a] Pazopanib ADVZ [BZ] | [a] Pazopanib Dr.Reddy's [RZ] |
| | | | | | | [a] Pazopanib-RZ [XT] | [a] Votrient [NV] |

**pazopanib 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2201W | 1 | 5 | 0.00 | 880.86 | 25.00 | [a] Pazopanib ADVZ [BZ] | [a] Pazopanib Dr.Reddy's [RZ] |
| | | | | | | [a] Pazopanib-RZ [XT] | [a] Votrient [NV] |

## PAZOPANIB

**Authority Required (STREAMLINED)**

***7458***

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**pazopanib 400 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10043N | 1 | 5 | 0.00 | 1,738.07 | 25.00 | [a] Pazopanib ADVZ [BZ] | [a] Pazopanib Dr.Reddy's [RZ] |
| | | | | | | [a] Pazopanib-RZ [XT] | [a] Votrient [NV] |

## PAZOPANIB

**Authority Required (STREAMLINED)**

***7458***

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**pazopanib 200 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10047T | 1 | 5 | 0.00 | 1,311.93 | 25.00 | [a] Pazopanib ADVZ [BZ] | [a] Pazopanib Dr.Reddy's [RZ] |
| | | | | | | [a] Pazopanib-RZ [XT] | [a] Votrient [NV] |

## PAZOPANIB

**Authority Required (STREAMLINED)**

***7459***

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**

- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**pazopanib 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10052C | 1 | 5 | 0.00 | 880.86 | 25.00 | [a] Pazopanib ADVZ [BZ] | [a] Pazopanib Dr.Reddy's [RZ] |
| | | | | | | [a] Pazopanib-RZ [XT] | [a] Votrient [NV] |

## PAZOPANIB

**Authority Required (STREAMLINED)**

***7459***

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**pazopanib 200 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10054E | 1 | 5 | 0.00 | 445.11 | 25.00 | [a] Pazopanib ADVZ [BZ] | [a] Pazopanib Dr.Reddy's [RZ] |
| | | | | | | [a] Pazopanib-RZ [XT] | [a] Votrient [NV] |

## PAZOPANIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***11974***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**Note** Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.

**Note** Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**pazopanib 200 mg tablet, 90**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2029T | 1 | 2 | 0.00 | 1,311.93 | 25.00 | [a] Pazopanib ADVZ [BZ] | [a] Pazopanib Dr.Reddy's [RZ] |
| | | | | | | [a] Pazopanib-RZ [XT] | [a] Votrient [NV] |

**pazopanib 400 mg tablet, 60**

| 2030W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 1,738.07 | 25.00 | [a] Pazopanib ADVZ [BZ] | [a] Pazopanib Dr.Reddy's [RZ] |
| | | | | | | [a] Pazopanib-RZ [XT] | [a] Votrient [NV] |

## PAZOPANIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***9247***
Advanced (unresectable and/or metastatic) soft tissue sarcoma
Treatment Phase: Initial treatment
**Clinical criteria:**

- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have received prior chemotherapy treatment including an anthracycline, **AND**
- Patient must not have received prior treatment with an angiogenesis inhibitor, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patient must not have any of the following conditions:
adipocytic soft tissue sarcoma;
gastrointestinal stromal tumour (GIST);
rhabdomyosarcoma other than alveolar or pleomorphic;
chondrosarcoma;
osteosarcoma;
Ewings tumour/primitive neuroectodermal tumour;
dermofibromatosis sarcoma protuberans;
inflammatory myofibroblastic sarcoma;
malignant mesothelioma;
mixed mesodermal tumour of the uterus.

**pazopanib 200 mg tablet, 90**

| 10042M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 1,311.93 | 25.00 | [a] Pazopanib ADVZ [BZ] | [a] Pazopanib Dr.Reddy's [RZ] |
| | | | | | | [a] Pazopanib-RZ [XT] | [a] Votrient [NV] |

**pazopanib 400 mg tablet, 60**

| 10041L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 1,738.07 | 25.00 | [a] Pazopanib ADVZ [BZ] | [a] Pazopanib Dr.Reddy's [RZ] |
| | | | | | | [a] Pazopanib-RZ [XT] | [a] Votrient [NV] |

## PAZOPANIB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***11937***
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Continuing treatment beyond 3 months
**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

**pazopanib 200 mg tablet, 90**

| 11252F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,311.93 | 25.00 | [a] Pazopanib ADVZ [BZ] | [a] Pazopanib Dr.Reddy's [RZ] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 11252F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| | | | | | | [a] Pazopanib-RZ [XT] | [a] Votrient [NV] |

**pazopanib 400 mg tablet, 60**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 11261Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| | 1 | 5 | 0.00 | 1,738.07 | 25.00 | [a] Pazopanib ADVZ [BZ] | [a] Pazopanib Dr.Reddy's [RZ] |
| | | | | | | [a] Pazopanib-RZ [XT] | [a] Votrient [NV] |

## REPOTRECTINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18244***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be documented in the patient's medical records:

(a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***13186***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**repotrectinib 40 mg capsule, 120**

| | | | | | | |
|---|---|---|---|---|---|---|
| 15280F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| | 1 | 3 | 0.00 | 7,811.21 | 25.00 | Augtyro [BQ] |

## REPOTRECTINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18244***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be documented in the patient's medical records:

(a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***13186***

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**repotrectinib 160 mg capsule, 60**

15288P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 9,822.36 | 25.00 | Augtyro [BQ] |

## RIPRETINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***12440***

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must not be resectable, **AND**
- The treatment must be as monotherapy, **AND**
- The condition must have progressed despite treatment with all drugs PBS-listed specifically for this PBS-indication; **OR**
- The condition must have progressed despite each of: (i) treatment with a drug PBS-listed specifically listed for this PBS-indication, (ii) an intolerance/expected intolerance to all other drugs PBS-listed for this specific PBS-indication, **AND**

- Patient must have a WHO performance status of 2 or less.

**Treatment criteria:**

- Patient must be undergoing PBS-subsidised treatment with this drug for the first time - retreatment/continuing treatment beyond the available repeat prescription is not permitted under this listing; see 'Continuing treatment' Treatment Phase listing to continue PBS-subsidised treatment in a patient without disease progression.

**Note** Currently PBS-listed drugs with the indication of: 'metastatic or unresectable malignant gastrointestinal stromal tumour' are: imatinib and sunitinib

**Authority Required**

***12455***

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must not be resectable, **AND**
- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be as monotherapy, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**ripretinib 50 mg tablet, 90**

12764T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 22,760.36 | 25.00 | Qinlock [ZB] |

## SELPERCATINIB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***19021***

Advanced or metastatic medullary thyroid cancer

**Clinical criteria:**

- The condition must be unresectable with documented disease progression prior to commencing treatment with this drug, **AND**
- The condition must have evidence of activating RET variants in tumour material - this evidence has been obtained prior to commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must be initiating treatment with this drug; **OR**
- Patient must be continuing treatment with this drug, with an absence of further disease progression while being treated with this drug.

Medical practitioners must prescribe the appropriate quantities of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks per dispensing, according to the specified dosage in the approved Therapeutic Goods Administration (TGA) Product Information (PI). A separate authority prescription form must be completed for each strength requested.

**Selpercatinib 40 mg tablet, 56**

15447B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 2,146.86 | 25.00 | Retevmo [LY] |

## SELPERCATINIB

**Note** Pharmaceutical benefits that have the forms Selpercatinib 40 mg tablet and Selpercatinib 40 mg capsule are equivalent for the purposes of substitution.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16270***

Locally advanced or metastatic non-small cell lung cancer

**Clinical criteria:**

- The condition must have evidence of rearranged during transfection (RET) gene fusion in tumour material - this evidence has been obtained prior to commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must be initiating treatment with this drug; **OR**
- Patient must be continuing treatment with this drug, with an absence of further disease progression while being treated with this drug.

Medical practitioners must prescribe the appropriate quantities of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks per dispensing, according to the specified dosage in the approved

Therapeutic Goods Administration (TGA) Product Information (PI). A separate authority prescription form must be completed for each strength requested.

**Selpercatinib 40 mg tablet, 56**

15371B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 2,146.86 | 25.00 | [a] Retevmo [LY] |

## SELPERCATINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***19048***

Advanced or metastatic medullary thyroid cancer

**Clinical criteria:**

- The condition must be unresectable with documented disease progression prior to commencing treatment with this drug, **AND**
- The condition must have evidence of activating RET variants in tumour material - this evidence has been obtained prior to commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must be initiating treatment with this drug; **OR**
- Patient must be continuing treatment with this drug, with an absence of further disease progression while being treated with this drug.

Medical practitioners must prescribe the appropriate quantities of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks per dispensing, according to the specified dosage in the approved Therapeutic Goods Administration (TGA) Product Information (PI). A separate authority prescription form must be completed for each strength requested.

Medical practitioners may prescribe selpercatinib 80 mg with a quantity of up to 56 units where the dose does not exceed 120 mg twice daily (i.e., in combination with selpercatinib 40 mg). Selpercatinib 80 mg with a quantity of 112 units must be prescribed only where the dose is 160 mg twice daily to provide 28 days of treatment per dispensing. Prescribers should refer to the TGA PI for dosing and dose adjustments regimens.

**Selpercatinib 80 mg tablet, 56**

15494L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *8,213.36 | 25.00 | Retevmo [LY] |

## SELPERCATINIB

**Note** Pharmaceutical benefits that have the forms Selpercatinib 80 mg tablet and Selpercatinib 80 mg capsule are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16282***

Locally advanced or metastatic non-small cell lung cancer

**Clinical criteria:**

- The condition must have evidence of rearranged during transfection (RET) gene fusion in tumour material - this evidence has been obtained prior to commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must be initiating treatment with this drug; **OR**
- Patient must be continuing treatment with this drug, with an absence of further disease progression while being treated with this drug.

Medical practitioners must prescribe the appropriate quantities of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks per dispensing, according to the specified dosage in the approved Therapeutic Goods Administration (TGA) Product Information (PI). A separate authority prescription form must be completed for each strength requested.

Medical practitioners may prescribe selpercatinib 80 mg with a quantity of up to 56 units where the dose does not exceed 120 mg twice daily (i.e., in combination with selpercatinib 40 mg). Selpercatinib 80 mg with a quantity of 112 units must be prescribed only where the dose is 160 mg twice daily to provide 28 days of treatment per dispensing. Prescribers should refer to the TGA PI for dosing and dose adjustments regimens.

**Selpercatinib 80 mg tablet, 56**

15416J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *8,213.36 | 25.00 | [a] Retevmo [LY] |

## SORAFENIB

**Authority Required (STREAMLINED)**

***7487***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

### sorafenib 200 mg tablet, 60

| 10242C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *4,222.50 | 25.00 | Nexavar [BN] |

## SORAFENIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***8621***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

### sorafenib 200 mg tablet, 60

| 10226F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *4,222.50 | 25.00 | Nexavar [BN] |

## SORAFENIB

**Note** Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.

Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17504***

Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**

- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A, **AND**
- The condition must be untreated with systemic therapy; **OR**
- Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to any of the following: (i) a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI), (ii) atezolizumab/bevacizumab combination therapy, (iii) durvalumab/tremelimumab combination therapy.

**Authority Required (STREAMLINED)**

***17436***

Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**sorafenib 200 mg tablet, 60**

| 9380Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *4,222.50 | 25.00 | Nexavar [BN] |

## SUNITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17862***

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have disease progression, **AND**
- The treatment must be as monotherapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**sunitinib 12.5 mg capsule, 28**

| 10009T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 509.46 | 25.00 | [a] Sunitinib Sandoz [SZ] | [a] Sutent [PF] |

**sunitinib 25 mg capsule, 28**

| 2842N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 1,015.87 | 25.00 | [a] ARX-Sunitinib [XT]<br>[a] Sutent [PF] | [a] Sunitinib Sandoz [SZ] |

**sunitinib 37.5 mg capsule, 28**

| 10473F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 1,508.73 | 25.00 | [a] ARX-Sunitinib [XT]<br>[a] Sutent [PF] | [a] Sunitinib Sandoz [SZ] |

**sunitinib 50 mg capsule, 28**

| 10010W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 2,026.44 | 25.00 | [a] ARX-Sunitinib [XT]<br>[a] Sutent [PF] | [a] Sunitinib Sandoz [SZ] |

## SUNITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***11878***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

**Note** Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

**Note** Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

**sunitinib 12.5 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9417P | 1 | 1 | 0.00 | 509.46 | 25.00 | [a] Sunitinib Sandoz [SZ] | [a] Sutent [PF] |

**sunitinib 25 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9418Q | 1 | 1 | 0.00 | 1,015.87 | 25.00 | [a] ARX-Sunitinib [XT] | [a] Sunitinib Sandoz [SZ] |
| | | | | | | [a] Sutent [PF] | |

**sunitinib 37.5 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10504W | 1 | 1 | 0.00 | 1,508.73 | 25.00 | [a] ARX-Sunitinib [XT] | [a] Sunitinib Sandoz [SZ] |
| | | | | | | [a] Sutent [PF] | |

**sunitinib 50 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9419R | 1 | 1 | 0.00 | 2,026.44 | 25.00 | [a] ARX-Sunitinib [XT] | [a] Sunitinib Sandoz [SZ] |
| | | | | | | [a] Sutent [PF] | |

## SUNITINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17614***

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be symptomatic (despite somatostatin analogues); **OR**
- Patient must have disease progression, **AND**
- The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease with any of: (i) everolimus; (ii) cabozantinib are not eligible to receive PBS-subsidised treatment with sunitinib for this condition.

Patients who have developed intolerance with any of: (i) everolimus; (ii) cabozantinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

**sunitinib 12.5 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10004M | 1 | 2 | 0.00 | 509.46 | 25.00 | [a] Sunitinib Sandoz [SZ] | [a] Sutent [PF] |

**sunitinib 25 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2959R | 1 | 2 | 0.00 | 1,015.87 | 25.00 | [a] ARX-Sunitinib [XT] | [a] Sunitinib Sandoz [SZ] |
| | | | | | | [a] Sutent [PF] | |

**sunitinib 37.5 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10464R | 1 | 2 | 0.00 | 1,508.73 | 25.00 | [a] ARX-Sunitinib [XT] | [a] Sunitinib Sandoz [SZ] |
| | | | | | | [a] Sutent [PF] | |

**sunitinib 50 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2837H | 1 | 2 | 0.00 | 2,026.44 | 25.00 | [a] ARX-Sunitinib [XT] | [a] Sunitinib Sandoz [SZ] |
| | | | | | | [a] Sutent [PF] | |

## SUNITINIB

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17856***

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib.

### sunitinib 12.5 mg capsule, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9420T | | | | | | | |
| NP | 1 | 3 | 0.00 | 509.46 | 25.00 | [a] Sunitinib Sandoz [SZ] | [a] Sutent [PF] |

### sunitinib 25 mg capsule, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9421W | | | | | | | |
| NP | 1 | 3 | 0.00 | 1,015.87 | 25.00 | [a] ARX-Sunitinib [XT] | [a] Sunitinib Sandoz [SZ] |
| | | | | | | [a] Sutent [PF] | |

### sunitinib 37.5 mg capsule, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10459L | | | | | | | |
| NP | 1 | 3 | 0.00 | 1,508.73 | 25.00 | [a] ARX-Sunitinib [XT] | [a] Sunitinib Sandoz [SZ] |
| | | | | | | [a] Sutent [PF] | |

### sunitinib 50 mg capsule, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9422X | | | | | | | |
| NP | 1 | 3 | 0.00 | 2,026.44 | 25.00 | [a] ARX-Sunitinib [XT] | [a] Sunitinib Sandoz [SZ] |
| | | | | | | [a] Sutent [PF] | |

## SUNITINIB

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***19250***

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must not be resectable, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have previously failed or be intolerant to imatinib mesilate.

Applications for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.

**sunitinib 12.5 mg capsule, 28**

| 9488J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 509.46 | 25.00 | [a] Sunitinib Sandoz [SZ] | [a] Sutent [PF] |

**sunitinib 25 mg capsule, 28**

| 9489K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 1,015.87 | 25.00 | [a] ARX-Sunitinib [XT] | [a] Sunitinib Sandoz [SZ] |
| | | | | | | [a] Sutent [PF] | |

**sunitinib 37.5 mg capsule, 28**

| 10503T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 1,508.73 | 25.00 | [a] ARX-Sunitinib [XT] | [a] Sunitinib Sandoz [SZ] |
| | | | | | | [a] Sutent [PF] | |

**sunitinib 50 mg capsule, 28**

| 9490L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 2,026.44 | 25.00 | [a] ARX-Sunitinib [XT] | [a] Sunitinib Sandoz [SZ] |
| | | | | | | [a] Sutent [PF] | |

## SUNITINIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS subsidised imatinib after progression on this drug

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17789***

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not be resectable, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**sunitinib 12.5 mg capsule, 28**

| 11266Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 509.46 | 25.00 | [a] Sunitinib Sandoz [SZ] | [a] Sutent [PF] |

**sunitinib 25 mg capsule, 28**

| 11253G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 1,015.87 | 25.00 | [a] ARX-Sunitinib [XT] | [a] Sunitinib Sandoz [SZ] |
| | | | | | | [a] Sutent [PF] | |

**sunitinib 37.5 mg capsule, 28**

| 11256K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 1,508.73 | 25.00 | [a] ARX-Sunitinib [XT]<br>[a] Sutent [PF] | [a] Sunitinib Sandoz [SZ] |

**sunitinib 50 mg capsule, 28**

| 11250D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 2,026.44 | 25.00 | [a] ARX-Sunitinib [XT]<br>[a] Sutent [PF] | [a] Sunitinib Sandoz [SZ] |

## MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES

### *CD38 (Clusters of Differentiation 38) inhibitors*

### DARATUMUMAB

**Note** This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17491***

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly)

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised).

**Treatment criteria:**

- Patient must be undergoing PBS-subsidised treatment with this drug once per lifetime. Meaning, patient must access this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been re-classified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), or irrespective of whether the disease staging has been changed (i.e. disease has changed from untreated multiple myeloma to relapsed or refractory multiple myeloma), (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment for the same PBS indication.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g)

must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

12683M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 8 | 0.00 | 6,925.33 | 25.00 | Darzalex SC [JC] |

## DARATUMUMAB

**Note** This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***12691***

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy from week 25 until disease progression (administered every 4 weeks)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

12725R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 6,925.33 | 25.00 | Darzalex SC [JC] |

## DARATUMUMAB

**Note** This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***12845***

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy for weeks 10 to 24 (administered every 3 weeks)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

12755H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | 0.00 | 6,925.33 | 25.00 | Darzalex SC [JC] |

## DARATUMUMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17661***

Untreated multiple myeloma

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 November 2025, **AND**
- Patient must have met all initial treatment PBS eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (a) the condition was newly diagnosed, (b) the condition was confirmed by a histological diagnosis, (c) the patient was/is ineligible for a stem cell transplant, (d) the treatment is being given as triple combination therapy limited only to: (i) this drug, (ii) lenalidomide, (iii) dexamethasone, (e) patient is not receiving concomitant PBS-subsidised treatment with bortezomib, carfilzomib, elotuzumab, pomalidomide, selinexor or thalidomide, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing PBS-subsidised treatment with this drug once per lifetime. Meaning, patient must access this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been re-classified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 24 weeks of treatment for the same PBS indication.

Details of the histological diagnosis of multiple myeloma, record of ineligibility for stem cell transplant and confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction to complete 24 weeks of treatment. For continuing PBS-subsidised treatment after week 24, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

15071F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 15 | 0.00 | 6,925.33 | 25.00 | Darzalex SC [JC] |

## DARATUMUMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17413***

Untreated multiple myeloma

Treatment Phase: Continuing treatment as first line drug therapy from week 25 onwards (administered once every four weeks)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy limited only to: (i) this drug, (ii) lenalidomide, and (iii) dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with bortezomib, carfilzomib, elotuzumab, pomalidomide, selinexor or thalidomide, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

15082T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 6,925.33 | 25.00 | Darzalex SC [JC] |

## DARATUMUMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17660***

Untreated multiple myeloma

Treatment Phase: Initial treatment as first-line drug therapy from week 0 to week 24

**Clinical criteria:**

- The condition must be newly diagnosed, **AND**

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- The treatment must form part of triple combination therapy limited only to: (i) this drug, (ii) lenalidomide, and (iii) dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with bortezomib, carfilzomib, elotuzumab, pomalidomide, selinexor or thalidomide.

**Treatment criteria:**

- Patient must be undergoing PBS-subsidised treatment with this drug once per lifetime. Meaning, patient must access this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been re-classified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 24 weeks of treatment for the same PBS indication.

Details of the histological diagnosis of multiple myeloma, record of ineligibility for stem cell transplant and confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

15088D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 15 | 0.00 | 6,925.33 | 25.00 | Darzalex SC [JC] |

## DARATUMUMAB

**Note** The intravenously administered presentation of this drug is not PBS listed for this indication at the request of the sponsor.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***13774***

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Continuing treatment from week 25 onwards (administered once every four weeks)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**
- Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

13199Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 6,925.33 | 25.00 | Darzalex SC [JC] |

## DARATUMUMAB

**Note** The intravenously administered presentation of this drug is not PBS listed for this indication at the request of the sponsor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 888 333.

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

PBS Authorities
GPO Box 9826
[Your capital city]

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**
***18406***
Newly diagnosed systemic light chain amyloidosis
Treatment Phase: Initial treatment from week 0 to week 24
**Clinical criteria:**

- The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis, **AND**
- The condition must be untreated with drug therapy, including this drug, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis), **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation.

**Treatment criteria:**

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**
- Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:
Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the name of pathologist/pathology provider, (ii) the site of biopsy
If the application is submitted through HPOS form upload or mail, it must include:
(i) details of the proposed prescription; and
(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**daratumumab 1.8 g/15 mL injection, 15 mL vial**

13202W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 15 | 0.00 | 6,925.33 | 25.00 | Darzalex SC [JC] |

## *HER2 (Human Epidermal Growth Factor Receptor 2) inhibitors*

### TRASTUZUMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***10212***
Early HER2 positive breast cancer
Treatment Phase: 3 weekly treatment regimen
**Clinical criteria:**

- Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant), **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; **OR**
- Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

10682F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 1,608.11 | 25.00 | Herceptin SC [RO] |

### TRASTUZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required (STREAMLINED)**
***9353***
Metastatic (Stage IV) HER2 positive breast cancer
Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must not be in combination with nab-paclitaxel, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10798H | 1 | 0 | 0.00 | 1,608.11 | 25.00 | Herceptin SC [RO] |

## TRASTUZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required (STREAMLINED)**

***9462***

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10803N | 1 | 3 | 0.00 | 1,608.11 | 25.00 | Herceptin SC [RO] |

### *PD-1/PD-L1 (Programmed cell death protein 1/death ligand 1) inhibitors*

## ATEZOLIZUMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***10216***

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing first-line treatment of metastatic disease - 3 weekly treatment regimen

**Treatment criteria:**

- Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment, **AND**
- Patient must have stable or responding disease.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14267X | 1 | 7 | 0.00 | 7,014.68 | 25.00 | Tecentriq SC [RO] |

## ATEZOLIZUMAB

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***10297***

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have stable or responding disease.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14288B | 1 | 7 | 0.00 | 7,014.68 | 25.00 | Tecentriq SC [RO] |

## ATEZOLIZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***10521***
Extensive-stage small cell lung cancer
Treatment Phase: Continuing treatment - 3 weekly treatment regimen
**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14225Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 4 | 0.00 | 7,014.68 | 25.00 | Tecentriq SC [RO] |

## ATEZOLIZUMAB

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***18242***
Locally advanced or metastatic non-small cell lung cancer
Treatment Phase: Initial treatment - 3 weekly treatment regimen
**Clinical criteria:**

- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy; **OR**
- The condition must have progressed after treatment with a prior targeted therapy PBS-listed for this condition.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14247W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 7,014.68 | 25.00 | Tecentriq SC [RO] |

## ATEZOLIZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***18257***
Extensive-stage small cell lung cancer
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must be previously untreated, **AND**
- Patient must not have previously received programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for any stage of small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be in combination with etoposide and a platinum-based antineoplastic drug.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14248X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 7,014.68 | 25.00 | Tecentriq SC [RO] |

## ATEZOLIZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***15455***
Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC)

Treatment Phase: 1,875 mg administered once every 3 weeks

**Population criteria:**

- Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; **OR**
- Patient must be continuing existing PBS-subsidised treatment with this drug; **OR**
- Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated.

**Clinical criteria:**

- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug, **AND**
- The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy, **AND**
- The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement, **AND**
- The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14269B | 1 | 7 | 0.00 | 7,014.68 | 25.00 | Tecentriq SC [RO] |

## ATEZOLIZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***10917***

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Continuing treatment of hepatocellular carcinoma - 3 weekly treatment regimen

**Treatment criteria:**

- Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14566P | 1 | 8 | 0.00 | 7,014.68 | 25.00 | Tecentriq SC [RO] |

## ATEZOLIZUMAB

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***18326***

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment 1

**Treatment criteria:**

- Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy.

**Clinical criteria:**

- The condition must be non-squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must not have previously been treated for this condition in the metastatic setting; **OR**
- The condition must have progressed after treatment with a prior targeted therapy PBS-listed for this condition, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**

- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

**Authority Required (STREAMLINED)**

***10125***

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment 2

**Treatment criteria:**

- Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy.

**Clinical criteria:**

- The condition must be non-squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, **AND**
- Patient must have progressive disease following treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) OR an anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor (TKI), **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14266W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 7,014.68 | 25.00 | Tecentriq SC [RO] |

## ATEZOLIZUMAB

**Caution** The safety of atezolizumab in combination with bevacizumab has not been established in patients who have incompletely treated varices, variceal bleeding within the previous 6 months or who are at high risk of bleeding. Patients should be assessed for risk of variceal bleeding prior to treatment with this combination.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***10939***

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Initial treatment

**Treatment criteria:**

- Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated.

**Clinical criteria:**

- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must not be suitable for transarterial chemoembolisation, **AND**
- Patient must have Child Pugh class A, **AND**
- The condition must be untreated with systemic therapy; **OR**
- Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.

**atezolizumab 1.875 g/15 mL injection, 15 mL vial**

14278L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 7,014.68 | 25.00 | Tecentriq SC [RO] |

### *Other monoclonal antibodies and antibody drug conjugates*

## ELRANATAMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18377***

Relapsed or refractory multiple myeloma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment with this drug for this condition, **AND**
- Patient must have had progressive disease after receiving at least 3 prior lines of therapy, including each of the following therapies: (i) a proteasome inhibitor, (ii) an immunomodulatory agent, and (iii) an anti-CD38 monoclonal antibody; **OR**

- Patient must have been refractory to, at least 3 prior lines of therapy, including each of the following therapies: (i) a proteasome inhibitor, (ii) an immunomodulatory agent, (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not have previously received treatment with another B-cell maturation antigen (BCMA) directed therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less prior to initiating treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Prescribers may request the number of vials in line with the dosing requirement for each stage of treatment with the intention of providing the number of vials for each 4-weeks of treatment (24-weeks of treatment including repeats). Up to 4 vials with 5 repeats may be requested for a patient undergoing treatment in weeks 2-26. Up to 2 vials with 5 repeats may be requested for a patient undergoing treatment from week 27 onwards. Requests beyond what is listed in the TGA approved product information will not be approved.

This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.

### Elranatamab 76 mg/1.9 mL injection, 1.9 mL vial

15293X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 6,291.12 | 25.00 | Elrexfio [PF] |

## ELRANATAMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18709***

Relapsed or refractory multiple myeloma

Treatment Phase: Induction treatment (step-up dosing)

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must have progressive disease after receiving at least 3 prior lines of therapy, including each of the following therapies: (i) a proteasome inhibitor, (ii) an immunomodulatory agent, and (iii) an anti-CD38 monoclonal antibody; **OR**
- Patient must be refractory to, at least 3 prior lines of therapy, including each of the following therapies: (i) a proteasome inhibitor, (ii) an immunomodulatory agent, (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have previously received treatment with another B-cell maturation antigen (BCMA) directed therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose.

Patients who require restarting therapy due to dose delays may access step-up dosing through this induction treatment restriction.

This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy.

**Elranatamab 44 mg/1.1 mL injection, 1.1 mL vial**

15300G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 3,698.28 | 25.00 | Elrexfio [PF] |

## EPCORITAMAB

**Caution** Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome (CRS).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16466***

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be discontinued in patients who experience disease progression whilst on treatment.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug administered weekly in cycles 1 to 3 - prescribe up to 9 repeats; **OR**
- Patient must be undergoing treatment with this drug administered fortnightly in cycles 4 to 9 - prescribe up to 5 repeats; **OR**
- Patient must be undergoing treatment with this drug administered every four weeks in cycles 10 and beyond - prescribe up to 2 repeats.

**Epcoritamab 48 mg/0.8 mL injection, 0.8 mL vial**

14819Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 9 | 0.00 | 9,547.75 | 25.00 | Epkinly [VE] |

## EPCORITAMAB

**Caution** Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome (CRS).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***19052***

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must have relapsed, or be refractory to, at least two prior systemic therapies, **AND**

- Patient must have a WHO performance status of no higher than 2, **AND**
- Patient must have previously received treatment with chimeric antigen receptor-T (CAR-T) cell therapy for this condition; **OR**
- Patient must be currently unable to receive treatment with CAR-T cell therapy for this condition, **AND**
- Patient must not be eligible for stem cell transplantation, **AND**
- Patient must not have received prior treatment with a PBS-subsidised CD20xCD3 bispecific monoclonal antibody (unless this is for a re-priming cycle with epcoritamab due to missed or delayed dose), **AND**
- The treatment must be discontinued in patients who experience disease progression whilst on treatment.

Prior systemic therapy may include autologous stem cell transplant.

Definition of patients unable to receive treatment with CAR-T cell therapy for this condition include geographical, psychosocial, clinical ineligibility or urgency.

**Note** A dose of 0.16 mg to be administered on Day 1 with initial 4 mg vial. A dose of 0.8 mg to be administered on Day 8 with the repeat 4 mg vial. Refer to the epcoritamab Therapeutic Goods Administration (TGA) approved Product Information.

**Epcoritamab 4 mg/0.8 mL injection, 0.8 mL vial**

14792M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 851.79 | 25.00 | Epkinly [VE] |

## OTHER ANTINEOPLASTIC AGENTS

### *Histone deacetylase (HDAC) inhibitors*

### VORINOSTAT

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***18425***

Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have received systemic treatment with chemotherapy, **AND**
- Patient must demonstrate relapsed or chemotherapy-refractory disease, **AND**
- Patient must be ineligible for stem cell transplant, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**vorinostat 100 mg capsule, 120**

11138F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 4,301.11 | 25.00 | Zolinza [MK] |

### VORINOSTAT

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***13246***

Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**vorinostat 100 mg capsule, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11141J | 1 | 1 | 0.00 | 4,301.11 | 25.00 | Zolinza [MK] |

## *Hedgehog pathway inhibitors*

## SONIDEGIB

**Caution** Sonidegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 20 months and 6 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18329***

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; **OR**
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and

(c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Inappropriate for surgery is defined as:**

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

**Inappropriate for curative radiotherapy is defined as:**

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18500***

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Confirmation from the treating doctor that the disease has not progressed; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Inappropriate for surgery is defined as:**

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

**Inappropriate for curative radiotherapy is defined as:**

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***7491***

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment or Continuing treatment

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**sonidegib 200 mg capsule, 30**

11304Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 7,711.33 | 25.00 | Odomzo [RA] |

## VISMODEGIB

**Caution** Vismodegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 24 months and 2 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18251***

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; **OR**
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and

(c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Inappropriate for surgery is defined as:**

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

**Inappropriate for curative radiotherapy is defined as:**

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18252***

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) Confirmation from the treating doctor that the disease has not progressed; and

(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Inappropriate for surgery is defined as:**

(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

(iii) Medical contraindication to surgery.

**Inappropriate for curative radiotherapy is defined as:**

(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

(ii) Limitations due to location of tumour; or

(iii) Limitations due to cumulative prior radiotherapy dose; or

(iv) Progressive disease despite prior irradiation of locally advanced BCC.

For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***7491***

Metastatic or locally advanced basal cell carcinoma (BCC)

Treatment Phase: Initial treatment or Continuing treatment

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**vismodegib 150 mg capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11070P | 1 | 3 | 0.00 | 7,206.06 | 25.00 | Erivedge [RO] |

## *Poly (ADP-ribose) polymerase (PARP) inhibitors*

### NIRAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17913***

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 tablets

**Clinical criteria:**

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**niraparib 100 mg tablet, 84**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14173Y NP | 1 | 5 | 0.00 | 10,038.87 | 25.00 | Zejula [GK] |

### NIRAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17800***

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 tablets

**Clinical criteria:**

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation), **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**niraparib 100 mg tablet, 84**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14190W | | | | | | |
| NP | 1 | 5 | 0.00 | 10,038.87 | 25.00 | Zejula [GK] |

## NIRAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17946***

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 tablets

**Clinical criteria:**

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**niraparib 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14196E | | | | | | |
| NP | 1 | 5 | 0.00 | 6,736.70 | 25.00 | Zejula [GK] |

## NIRAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17912***

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 tablets

**Clinical criteria:**

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation), **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**niraparib 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14206Q | | | | | | |
| NP | 1 | 5 | 0.00 | 6,736.70 | 25.00 | Zejula [GK] |

## NIRAPARIB

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Note** Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15440***

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 tablets

**Clinical criteria:**

- The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test, **AND**
- The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 genes - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; **OR**
- The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug class for the first time; **OR**
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.

Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.

**niraparib 100 mg tablet, 56**

| 14172X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 6,736.70 | 25.00 | Zejula [GK] |

## NIRAPARIB

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Note** Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15414***

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 tablets

**Clinical criteria:**

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 gene(s) - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug class for the first time; **OR**
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

**niraparib 100 mg tablet, 56**

| 14179G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 6,736.70 | 25.00 | Zejula [GK] |

## NIRAPARIB

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Note** Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15441***

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 tablets

**Clinical criteria:**

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 gene(s) - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug class for the first time; **OR**
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

**niraparib 100 mg tablet, 84**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14207R | 1 | 2 | 0.00 | 10,038.87 | 25.00 | Zejula [GK] |

## NIRAPARIB

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Note** Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15408***

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 tablets

**Clinical criteria:**

- The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test, **AND**
- The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 genes - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; **OR**
- The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug class for the first time; **OR**
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.

Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.

**niraparib 100 mg tablet, 84**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14212B | 1 | 2 | 0.00 | 10,038.87 | 25.00 | Zejula [GK] |

## OLAPARIB

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17910***

High grade epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of subsequent-line maintenance therapy (BRCA1/2 gene mutation)

**Clinical criteria:**

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial subsequent-line maintenance therapy (BRCA1/2 gene mutation), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

**olaparib 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11503K NP | 2 | 5 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11539H NP | 2 | 5 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

## OLAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17945***

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (BRCA1/2 gene mutation)

**Clinical criteria:**

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation), **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**olaparib 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12169L NP | 2 | 5 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12161C NP | 2 | 5 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

## OLAPARIB

**Note** Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***14761***

High grade epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial subsequent-line maintenance therapy (BRCA1/2 gene mutation)

**Clinical criteria:**

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 gene(s) - this has been confirmed by a validated test, **AND**
- The condition must be platinum sensitive, **AND**
- Patient must have received at least two previous platinum-containing regimens, **AND**
- Patient must have relapsed following a previous platinum-containing regimen, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

**olaparib 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11522K | 2 | 2 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11528R | 2 | 2 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

## OLAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17796***

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**olaparib 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12921C NP | 2 | 5 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12913P NP | 2 | 5 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

## OLAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***12590***

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug, **AND**
- The condition must have progressed following prior treatment that included a novel hormonal drug for this condition (metastatic/non-metastatic disease), **AND**
- Patient must have a WHO performance status of 2 or less.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug for the first time.

**olaparib 100 mg tablet, 56**

| 12932P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| 12929L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

## OLAPARIB

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Note** Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***14741***

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation)

**Clinical criteria:**

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 gene(s) - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug class for the first time; **OR**
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

**olaparib 100 mg tablet, 56**

| 12170M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| 12157W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

## OLAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17911***

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation)

**Clinical criteria:**

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**

- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**olaparib 100 mg tablet, 56**

| 13782J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| 13807Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

## OLAPARIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17981***

Early breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug as adjuvant therapy for this condition, **AND**
- Patient must not have developed disease recurrence while receiving treatment with this drug for this condition, **AND**
- The treatment must not be a PBS-subsidised benefit beyond a total of 52 weeks of treatment (including any non-PBS-subsidised supply), **AND**
- The treatment must not in combination with any of the following: (i) abemaciclib, (ii) pembrolizumab, (iii) ribociclib.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**olaparib 100 mg tablet, 56**

| 14216F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 6 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| 14215E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 6 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

## OLAPARIB

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16780***

Early breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must have received neoadjuvant or adjuvant chemotherapy, **AND**
- The treatment must be adjuvant to surgical resection, **AND**
- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene variant, **AND**
- Patient must have received neoadjuvant chemotherapy, and residual invasive cancer is confirmed in the breast and/or resected lymph nodes (pathological complete response was not achieved); **OR**
- Patient must have received adjuvant chemotherapy for triple negative breast cancer, and has either: (a) node positive disease is present, (b) a primary tumour greater than 20 mm; **OR**

- Patient must have received adjuvant chemotherapy for hormone receptor positive breast cancer, and has at least 4 positive lymph nodes, **AND**
- The treatment must not be a PBS-subsidised benefit beyond the following, whichever comes first: (i) a total of 52 weeks of treatment (including any non-PBS-subsidised supply), (ii) disease recurrence. Mark any remaining repeat prescriptions with the word 'cancelled' where (i)/(ii) has occurred, **AND**
- The treatment must be commenced within 12 weeks of completing other therapy noting that other therapy can be any of the following therapy: (i) surgery, (ii) radiotherapy, (iii) chemotherapy, **AND**
- The treatment must not in combination with any of the following: (i) abemaciclib, (ii) pembrolizumab, (iii) ribociclib.

Retain all pathology imaging and investigative test results in the patient's medical records.

Treatment with this drug for this condition is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under metastatic disease is no longer available).

**olaparib 100 mg tablet, 56**

| 14181J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| 14208T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

## OLAPARIB

**Note** This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

**Note** Definitions:

Class 5 - Pathogenic

Class 4 - Likely pathogenic

Tier I - variants of strong clinical significance

Tier II - variants of potential clinical significance

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15141***

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation)

**Clinical criteria:**

- The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test, **AND**
- The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 genes - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; **OR**
- The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug class for the first time; **OR**
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.

Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.

**olaparib 100 mg tablet, 56**

| 13783K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| 13800H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

## OLAPARIB

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17909***

Metastatic breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene variant, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- Patient must have received chemotherapy in the neoadjuvant, adjuvant or metastatic setting, **AND**
- Patient must not have received PBS-subsidised treatment with this drug in any earlier line of treatment for breast cancer, **AND**
- The condition must be triple negative breast cancer; **OR**
- The condition must be hormone-receptor positive breast cancer and the patient has either: (i) progressive disease after receiving endocrine therapy, (ii) been considered inappropriate for endocrine therapy, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

**Treatment criteria:**

- Must be treated by a medical practitioner.

Retain all pathology imaging and investigative test results in the patient's medical records. Do not submit copies of these as part of the authority application.

Treatment with this drug for this condition is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under metastatic disease is no longer available).

**Authority Required**

***18002***

Metastatic breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received previous PBS-subsidised treatment with this drug in the metastatic setting, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**olaparib 100 mg tablet, 56**

| 14689D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

**olaparib 150 mg tablet, 56**

| 14687B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *6,754.26 | 25.00 | Lynparza [AP] |

## TALAZOPARIB

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17867***

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- Patient must not have received prior PBS-subsidised novel hormonal drug in any non-metastatic setting of prostate cancer prior to commencing treatment with this drug for this condition, **AND**

- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance score no higher than 1 prior to treatment initiation, **AND**
- Patient must be undergoing concurrent treatment with enzalutamide, unless an intolerance to enzalutamide requires either a: (i) temporary cessation, (ii) permanent discontinuation, **AND**
- The treatment must not be a PBS-subsidised benefit beyond disease progression.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Talazoparib 100 microgram capsule, 30**

| 14685X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,667.48 | 25.00 | Talzenna [PF] |

**talazoparib 250 microgram capsule, 30**

| 14684W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,667.48 | 25.00 | Talzenna [PF] |

**Talazoparib 350 microgram capsule, 30**

| 14690E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,667.48 | 25.00 | Talzenna [PF] |

**Talazoparib 500 microgram capsule, 30**

| 14683T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,667.48 | 25.00 | Talzenna [PF] |

### *Isocitrate dehydrogenase (IDH) inhibitors*

## IVOSIDENIB

**Caution** Ivosidenib can cause dose-dependent prolongation of the heart rate-corrected QT (QTc) interval. At treatment initiation patients should undergo an electrocardiogram (ECG) to assess the heart rate-corrected QT (QTc) interval. Dose interruptions are recommended until QTc returns to no more than 480 msec. Monitor ECGs at least weekly for two weeks following return of QTc. Permanently discontinue ivosidenib if QTc poses life threatening ventricular arrhythmia (Grade 4).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16701***

Locally advanced or metastatic cholangiocarcinoma

**Clinical criteria:**

- Patient must have a test of tumour tissue confirming the presence of an IDH1 R132 variant, **AND**
- Patient must have had systemic therapy for this condition prior to initiating treatment with this drug for this condition, **AND**
- Patient must have/have had a WHO performance status of 2 or less at treatment initiation with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Confirm that evidence of the presence of a pathogenic variant of the IDH1 gene is documented/retained in the patient's medical records once only with the first PBS prescription.

**ivosidenib 250 mg tablet, 60**

| 14868M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 20,252.36 | 25.00 | Tibsovo [SE] |

## VORASIDENIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***19016***

Adult-type IDH-mutant astrocytoma or oligodendroglioma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a World Health Organisation (WHO) Grade 2 astrocytoma or oligodendroglioma, **AND**
- Patient must have a test of tumour tissue confirming the presence of a susceptible isocitrate dehydrogenase-1 (IDH1) variant or isocitrate dehydrogenase-2 (IDH2) variant, **AND**

- Patient must have residual or recurrent disease after at least one prior surgery (biopsy, sub-total resection, or gross total resection) for this condition, **AND**
- Patient must not be in immediate need of radiotherapy and/or chemotherapy for this condition, **AND**
- The condition must not have been previously treated with systemic anticancer therapy or radiotherapy, **AND**
- Patient must have either a: (i) Karnofsky Performance Score of at least 80%, (ii) Lansky Performance Score of at least 80%.

Confirm that evidence of the presence of a susceptible IDH1 or IDH2 variant in the tumour tissue is documented/retained in the patient's medical records once only with the first PBS prescription.

**Authority Required (STREAMLINED)**

***19035***

Adult-type IDH-mutant astrocytoma or oligodendroglioma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Authority Required (STREAMLINED)**

***18999***

Adult-type IDH-mutant astrocytoma or oligodendroglioma

Treatment Phase: Grandfather arrangements - Transitioning from non-PBS to PBS-subsidised treatment

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2026, **AND**
- Patient must have a World Health Organisation (WHO) Grade 2 astrocytoma or oligodendroglioma, **AND**
- Patient must have had a susceptible isocitrate dehydrogenase-1 (IDH1) mutation or isocitrate dehydrogenase-2 (IDH2) mutation at the time of initiation of non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, at initiation of non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had residual or recurrent disease after at least one prior surgery (biopsy, sub-total resection, or gross total resection) for this condition at the time of initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not have been previously treated with systemic anticancer therapy prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Confirm that evidence of the presence of a susceptible IDH1 or IDH2 variant in the tumour tissue is documented/retained in the patient's medical records once only with the first PBS prescription.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Vorasidenib 10 mg tablet, 30**

15437L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *28,947.36 | 25.00 | Voranigo [SE] |

**Vorasidenib 40 mg tablet, 30**

15461R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 28,724.36 | 25.00 | Voranigo [SE] |

## *Other antineoplastic agents*

## BELZUTIFAN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16215***

Von Hippel-Lindau (VHL) disease

Treatment Phase: Initiating or recommencing treatment

**Clinical criteria:**

- The condition must have been diagnosed by at least one of: (i) a germline VHL alteration; (ii) at least two manifestations highly characteristic of VHL disease; (iii) at least one manifestation highly characteristic of VHL disease with a documented family history of VHL, **AND**
- The condition must be at least one of: (i) VHL-associated non-metastatic renal cell carcinoma (RCC); (ii) VHL-associated central nervous system (CNS) haemangioblastoma; (iii) VHL-associated non-metastatic pancreatic neuroendocrine tumour (pNET), **AND**

- Patient must not have tumour(s) that require immediate surgery as assessed by the treating clinician, **AND**
- Patient must be untreated with this drug for this condition; **OR**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for a different tumour type; **OR**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition and ceased previous treatment for family planning purposes, **AND**
- Patient must have WHO performance status no higher than 1; **OR**
- The condition must be VHL-associated brainstem tumour(s), or brain herniation, which temporarily affected the patient's WHO performance status to be higher than 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for VHL disease associated tumours.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of VHL disease associated tumours.

Patients who cease therapy for reasons other than, clinical disease progression or metastasis, may re-initiate PBS-subsidised treatment through the initiating or recommencing treatment phase.

For the purpose of administering this restriction, the highly characteristic manifestations of VHL disease include but not limited to:

(i) retinal, spinal, or cerebellar haemangioblastoma;

(ii) adrenal or extra-adrenal phaeochromocytoma;

(iii) renal cell carcinoma;

(iv) multiple renal and pancreatic cysts;

(v) endolymphatic sac tumours, papillary cystadenomas of the epididymis or broad ligament, or pancreatic neuroendocrine tumours.

**Authority Required**

***16180***

Von Hippel-Lindau (VHL) disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same tumour type, **AND**
- Patient must not have developed VHL-associated metastatic disease, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of the condition while being treated with this drug, the details of which must be kept with the patient's record, **AND**
- The treatment must be the sole PBS-subsidised therapy for VHL disease associated tumours.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of VHL disease associated tumours.

Patients who cease therapy for reasons other than, clinical disease progression or metastasis, may re-initiate PBS-subsidised treatment through the initiating or recommencing treatment phase.

For the purpose of administering this restriction, clinical improvement or stabilisation of the patient's condition includes but is not limited to:

(i) avoidance of surgery;

(ii) avoidance of renal replacement therapy such as dialysis or renal transplantation in patients with VHL- associated renal cell carcinoma (RCC);

(iii) experiencing clinical benefit in at least one of the VHL associated conditions, as determined by the treating clinician(s).

### belzutifan 40 mg tablet, 90

14665W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 22,392.36 | 25.00 | Welireg [MK] |

## HYDROXYCARBAMIDE

**Restricted benefit**

***17848***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

### hydroxycarbamide (hydroxyurea) 500 mg capsule, 100

3093T

NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 47.65 | 25.00 | [a] Hydrea [LM] | [a] HYDROXYCARBAMIDE MEDSURGE [DZ] |

## VENETOCLAX

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***12462***

Acute Myeloid Leukaemia

**Clinical criteria:**

- The condition must be previously untreated at the time of initiation with this drug (except for essential treatment with hydroxyurea or leukapheresis), **AND**
- Patient must not be considered eligible for standard intensive remission induction chemotherapy at the time of initiation with this drug, **AND**
- The treatment must be used in combination with azacitidine (refer to Product Information for timing of azacitidine and venetoclax doses), **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not be acute promyelocytic leukaemia.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**venetoclax 50 mg tablet, 7**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12773G | 4 | 2 | 0.00 | *934.64 | 25.00 | Venclexta [VE] |

**venetoclax 100 mg tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12803W | 1 | 2 | 0.00 | 7,519.07 | 25.00 | Venclexta [VE] |

## VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***11069***

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with rituximab for up to a maximum of 6 cycles, followed by monotherapy, **AND**
- The treatment must be ceased on disease progression or on completion of 24 months of PBS-subsidised treatment under this restriction with this drug for this condition, whichever comes first.

**venetoclax 100 mg tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11639N | 1 | 5 | 0.00 | 7,519.07 | 25.00 | Venclexta [VE] |

## VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***10995***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Dose modification

**Clinical criteria:**

- The treatment must be for dose titration purposes.

**venetoclax 10 mg tablet, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12999E | 7 | 0 | 0.00 | *102.48 | 25.00 | Venclexta [VE] |

**venetoclax 50 mg tablet, 7**

| 11648C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 240.68 | 25.00 | Venclexta [VE] |

## VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18665***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Second and final continuing treatment prescription (treatment cycles 7 to 12 inclusive) of first-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must cease upon disease progression; **OR**
- The treatment must cease upon completion of 12 cycles of treatment with this drug for this condition, whichever comes first, **AND**
- The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses), **AND**
- The treatment must not be in combination with acalabrutinib.

**venetoclax 100 mg tablet, 120**

| 12199C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 7,519.07 | 25.00 | Venclexta [VE] |

## VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18687***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First continuing treatment (treatment cycles 2 to 6 inclusive) of first-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses), **AND**
- The treatment must not be in combination with acalabrutinib, **AND**
- The treatment must cease upon disease progression.

**venetoclax 100 mg tablet, 120**

| 12205J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 4 | 0.00 | 7,519.07 | 25.00 | Venclexta [VE] |

## VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15907***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First continuing treatment (treatment cycles 5 to 9 inclusive) of first-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with ibrutinib (refer to Product Information for timing of ibrutinib and venetoclax doses), **AND**
- The treatment must cease upon disease progression.

**venetoclax 100 mg tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14585P | 1 | 4 | 0.00 | 7,519.07 | 25.00 | Venclexta [VE] |

## VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15904***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Second and final continuing treatment prescription (treatment cycles 10 to 15 inclusive) of first-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with ibrutinib (refer to Product Information for timing of ibrutinib and venetoclax doses), **AND**
- The treatment must cease upon disease progression; **OR**
- The treatment must cease upon completion of 12 cycles of treatment with this drug for this condition, whichever comes first.

**venetoclax 100 mg tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14595E | 1 | 5 | 0.00 | 7,519.07 | 25.00 | Venclexta [VE] |

## VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18648***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: First continuing treatment (treatment cycles 4 to 8 inclusive) of first-line therapy with acalabrutinib

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with acalabrutinib, **AND**
- The treatment must not be in combination with obinutuzumab, **AND**
- The treatment must cease upon disease progression.

**venetoclax 100 mg tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15357G | 1 | 4 | 0.00 | 7,519.07 | 25.00 | Venclexta [VE] |

## VENETOCLAX

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18667***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Second and final continuing treatment (treatment cycles 9 to 14 inclusive) of first-line therapy with acalabrutinib

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with acalabrutinib, **AND**
- The treatment must not be in combination with obinutuzumab, **AND**
- The treatment must not exceed 12 cycles in total with this drug, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first.

**venetoclax 100 mg tablet, 120**

15358H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 7,519.07 | 25.00 | Venclexta [VE] |

## VENETOCLAX

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***14776***

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Dose titration for relapsed/refractory disease

**Clinical criteria:**

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition.

**Treatment criteria:**

- Patient must not be undergoing retreatment with this drug where any of: (i) prior treatment of CLL/SLL with this same drug was unable to prevent disease progression; (ii) 24 months of PBS-subsidised treatment has been administered with this drug for this condition.

**venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack**

11630D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 0 | 0.00 | 1,707.53 | 25.00 | Venclexta [VE] |

## VENETOCLAX

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18683***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment in first-line therapy - Dose titration (weeks 1 to 4 of a 5-week ramp-up schedule)

**Clinical criteria:**

- The condition must be untreated with drug treatment at the time of the first dose of this drug; **OR**
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses), **AND**
- The treatment must not be in combination with acalabrutinib.

**venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack**

12188L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 0 | 0.00 | 1,707.53 | 25.00 | Venclexta [VE] |

## VENETOCLAX

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15905***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment in first-line therapy with ibrutinib - Dose titration (cycle 4)

**Clinical criteria:**

- The condition must be untreated with venetoclax at the time of the first dose of this drug, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be in combination with ibrutinib (refer to Product Information for timing of ibrutinib and venetoclax doses).

**venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack**

14584N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 0 | 0.00 | 1,707.53 | 25.00 | Venclexta [VE] |

## VENETOCLAX

**Note** The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18666***

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment in first-line therapy with acalabrutinib - Dose titration (cycle 3)

**Clinical criteria:**

- The condition must be untreated with venetoclax at the time of the first dose of this drug; **OR**
- Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be in combination with acalabrutinib, **AND**
- The treatment must not be in combination with obinutuzumab.

**venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack**

15361L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 0 | 0.00 | 1,707.53 | 25.00 | Venclexta [VE] |

# ENDOCRINE THERAPY

## HORMONES AND RELATED AGENTS

### *Progestogens*

### MEDROXYPROGESTERONE

**Restricted benefit**

***17880***

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Restricted benefit**

***17881***

Endometrial cancer

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**medroxyprogesterone acetate 100 mg tablet, 100**

| 2725K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 85.11 | 25.00 | Provera [PF] |

**medroxyprogesterone acetate 200 mg tablet, 60**

| 2316X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 95.05 | 25.00 | Provera [PF] |

**medroxyprogesterone acetate 250 mg tablet, 60**

| 2727M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 97.50 | 25.00 | Provera [PF] |

### MEDROXYPROGESTERONE

**Restricted benefit**

***17958***

Breast cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Restricted benefit**

***17923***

Endometrial cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**medroxyprogesterone acetate 100 mg tablet, 100**

| 14067J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *157.94 | 25.00 | Provera [PF] |

**medroxyprogesterone acetate 200 mg tablet, 60**

| 13881N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *178.80 | 25.00 | Provera [PF] |

**medroxyprogesterone acetate 250 mg tablet, 60**

| 13961T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *183.96 | 25.00 | Provera [PF] |

## *Gonadotropin releasing hormone analogues*

### GOSERELIN

**Restricted benefit**

***17811***

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be locally advanced (stage C); **OR**
- The condition must be metastatic (stage D).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**goserelin 10.8 mg implant, 1**

| 8093Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 694.32 | 25.00 | Zoladex 10.8 Implant [AP] |

### GOSERELIN

**Restricted benefit**

***17811***

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be locally advanced (stage C); **OR**
- The condition must be metastatic (stage D).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Restricted benefit**

***18025***

Endometriosis

**Clinical criteria:**

- The condition must be visually proven, **AND**
- The treatment must be for the short-term (up to 6 months).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Note** Only 1 course of not more than 6 months' therapy will be authorised.

**Restricted benefit**

***17880***

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Restricted benefit**

***17956***

Anticipated premature ovarian failure

**Clinical criteria:**

- Patient must be receiving treatment with an alkylating agent for a malignancy or an autoimmune disorder that has a high risk of causing premature ovarian failure, **AND**
- Patient must not receive more than 6 months' of treatment for this condition in a lifetime.

**Population criteria:**

- Patient must be pre-menopausal.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**

- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**goserelin 3.6 mg implant, 1**

| 1454M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 207.94 | 25.00 | Zoladex Implant [AP] |

## GOSERELIN (&) BICALUTAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**
***17814***
Carcinoma of the prostate
**Clinical criteria:**

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**goserelin 3.6 mg implant [1] (&) bicalutamide 50 mg tablet [28], 1 pack**

| 9064C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 402.48 | 25.00 | ZolaCos CP 3.6/50 [AP] |

**goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28], 1 pack**

| 9065D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 1,029.35 | 25.00 | ZolaCos CP 10.8/50(28) [AP] |

**goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [84], 1 pack**

| 9066E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 1,316.27 | 25.00 | ZolaCos CP 10.8/50(84) [AP] |

## LEUPRORELIN

**Restricted benefit**
***17812***
Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate
**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

| 8707G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 264.04 | 25.00 | Eligard 1 month [MF] |

**leuprorelin acetate 7.5 mg modified release injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber syringe**

| 8875D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 264.04 | 25.00 | Lucrin Depot 7.5mg PDS [VE] |

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

| 8708H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 694.32 | 25.00 | Eligard 3 month [MF] |

**leuprorelin acetate 22.5 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

| 8876E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 694.32 | 25.00 | Lucrin Depot 3 Month PDS [VE] |

**leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

| 8709J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 922.22 | 25.00 | Eligard 4 month [MF] |

**leuprorelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

| 8877F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 922.22 | 25.00 | Lucrin Depot 4 Month PDS [VE] |

**leuprorelin acetate 45 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

| 8859G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 1,371.62 | 25.00 | Eligard 6 month [MF] |

**leuprorelin acetate 45 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

| 11943N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 1,371.62 | 25.00 | Lucrin Depot 6-Month [VE] |

## LEUPRORELIN

**Restricted benefit**

***12351***

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

**leuprorelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

| 11944P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 693.50 | 25.00 | Lucrin Depot Paediatric 30 mg PDS [VE] |

## LEUPRORELIN

**Restricted benefit**

***13624***

Central precocious puberty

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; **OR**
- Must be treated by an endocrinologist specialising in paediatrics.

**Population criteria:**

- Patient must be of an age that is prior to their 10th birthday if female; **OR**
- Patient must be of an age that is prior to their 11th birthday if male
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 8th birthday if female; **OR**
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if male.

**leuprorelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

| 11960L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 693.50 | 25.00 | Lucrin Depot Paediatric 30 mg PDS [VE] |

## LEUPRORELIN

**Restricted benefit**

***13624***

Central precocious puberty

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; **OR**
- Must be treated by an endocrinologist specialising in paediatrics.

**Population criteria:**

- Patient must be of an age that is prior to their 10th birthday if female; **OR**
- Patient must be of an age that is prior to their 11th birthday if male
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 8th birthday if female; **OR**

- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if male.

**Restricted benefit**

***12351***

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

**leuprorelin acetate 45 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13187C | 1 | 0 | 0.00 | 1,371.62 | 25.00 | Eligard 6 month [MF] |

## LEUPRORELIN (&) BICALUTAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***17814***

Carcinoma of the prostate

**Clinical criteria:**

- The condition must be metastatic (stage D), **AND**
- Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10962Y | | | | | | |
| NP | ‡1 | 5 | 0.00 | 406.41 | 25.00 | Bi ELIGARD CP [MF] |

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10963B | | | | | | |
| NP | ‡1 | 0 | 0.00 | 959.95 | 25.00 | Bi ELIGARD CP [MF] |

**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [84], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10969H | | | | | | |
| NP | ‡1 | 1 | 0.00 | 1,098.67 | 25.00 | Bi ELIGARD CP [MF] |

## TRIPTORELIN

**Note** The listing of this medicine is not for use in gender dysphoria in minors.

**triptorelin 3.75 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9378N | | | | | | |
| NP | 1 | 5 | 0.00 | 207.94 | 25.00 | Diphereline [IS] |

## TRIPTORELIN

**Restricted benefit**

***17812***

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**triptorelin 11.25 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9379P | | | | | | |
| NP | 1 | 1 | 0.00 | 694.41 | 25.00 | Diphereline [IS] |

## TRIPTORELIN

**Restricted benefit**

***17812***

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**Restricted benefit**

***12387***

Central precocious puberty

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; **OR**
- Must be treated by an endocrinologist specialising in paediatrics.

**Population criteria:**

- Patient must be of an age that is prior to their 12th birthday if female; **OR**
- Patient must be of an age that is prior to their 13th birthday if male
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if female; **OR**
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 10th birthday if male.

**Restricted benefit**

***12351***

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

**triptorelin 22.5 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack**

5297T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 1,371.68 | 25.00 | Diphereline [IS] |

NP

# HORMONE ANTAGONISTS AND RELATED AGENTS

## *Anti-estrogens*

## FULVESTRANT

**Authority Required (STREAMLINED)**

***17918***

Locally advanced or metastatic breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable.

**Population criteria:**

- Patient must not be premenopausal.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**fulvestrant 250 mg/5 mL injection, 2 x 5 mL syringes**

12300J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 156.77 | 25.00 | [a] FULVESTRANT ACCORD [OC]<br>[a] FULVESTRANT EVER PHARMA [IT]<br>[a] Fulvestrant SXP [XN] | [a] FULVESTRANT-AFT [AE]<br>[a] Fulvestrant Sandoz [SZ] |

NP

## TAMOXIFEN

**Note** For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

**Restricted benefit**

***5522***

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

### tamoxifen 20 mg tablet, 30

| 1880Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 7.80 | *31.44 | 25.00 | [a] Nolvadex-D [AP] |

## TAMOXIFEN

**Note** For item codes 13960R and 13997Q, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

**Restricted benefit**

***14895***

Breast cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

### tamoxifen 20 mg tablet, 30

| 13960R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 15.60 | *48.52 | 25.00 | [a] Nolvadex-D [AP] |

## TAMOXIFEN

**Note** This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

**Note** For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

**Restricted benefit**

***5522***

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

### tamoxifen 20 mg tablet, 60

| 2110C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 23.54 | 25.00 | [a] Genox 20 [AF] | [a] GenRx Tamoxifen [GX] |
| | | | | | | [a] Tamosin [OX] | [a] Tamoxifen Sandoz [SZ] |

## TAMOXIFEN

**Note** This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

**Note** For item codes 13960R and 13997Q, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

**Restricted benefit**

***14895***

Breast cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

### tamoxifen 20 mg tablet, 60

| 13997Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *32.72 | 25.00 | [a] Genox 20 [AF] | [a] GenRx Tamoxifen [GX] |
| | | | | | | [a] Tamosin [OX] | [a] Tamoxifen Sandoz [SZ] |

## TAMOXIFEN

**Note** A moderate risk of developing breast cancer is if the lifetime breast cancer risk is 1.5 to 3 times the population average. A high risk of developing breast cancer is if the lifetime breast cancer risk is more than 3 times the population average.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***16579***
Reduction of breast cancer risk

**Clinical criteria:**

- Patient must have a moderate or high risk of developing breast cancer, **AND**
- The treatment must not exceed a dose of 20 mg per day, **AND**
- The treatment must not exceed a lifetime maximum of 5 years for this condition.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**tamoxifen 20 mg tablet, 30**

| 10911G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.00 | 20.54 | [a] Genox 20 [AF] | |
| | | | [B]3.90 | 22.90 | 20.54 | [a] Nolvadex-D [AP] | |

## TAMOXIFEN

**Note** A moderate risk of developing breast cancer is if the lifetime breast cancer risk is 1.5 to 3 times the population average. A high risk of developing breast cancer is if the lifetime breast cancer risk is more than 3 times the population average.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***16664***
Reduction of breast cancer risk

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have a moderate or high risk of developing breast cancer, **AND**
- The treatment must not exceed a dose of 20 mg per day, **AND**
- The treatment must not exceed a lifetime maximum of 5 years for this condition.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**tamoxifen 20 mg tablet, 30**

| 13906X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *23.64 | 25.00 | [a] Genox 20 [AF] | |
| | | | [B]7.80 | *31.44 | 25.00 | [a] Nolvadex-D [AP] | |

### *Anti-androgens*

## APALUTAMIDE

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17875***
Castration resistant non-metastatic carcinoma of the prostate

**Clinical criteria:**

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); **OR**
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**Treatment criteria:**

- Patient must be undergoing concurrent treatment with androgen deprivation therapy, **AND**
- Must be treated by a medical practitioner; **OR**

- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

**apalutamide 60 mg tablet, 120**

| 12992T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,756.73 | 25.00 | Erlyand [JC] |

## APALUTAMIDE

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17877***

Metastatic castration sensitive carcinoma of the prostate

**Clinical criteria:**

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); **OR**
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**Treatment criteria:**

- Patient must be undergoing concurrent androgen deprivation therapy, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**apalutamide 60 mg tablet, 120**

| 13288J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,756.73 | 25.00 | Erlyand [JC] |

## BICALUTAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***5729***

Metastatic (stage D) carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**bicalutamide 50 mg tablet, 28**

| 8094B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 52.27 | 25.00 | [a] APO-Bicalutamide [TX] | [a] Bicalox [ZS] |
| | | | | | | [a] Calutex [AS] | [a] Cosamide 50 [AF] |
| | | | | | | [a] Cosudex [AP] | |

## CYPROTERONE

**cyproterone acetate 50 mg tablet, 50**

| 1270W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *73.92 | 25.00 | [a] ANTERONE 50 [RW] | [a] Cyproterone Sandoz [HX] |
| | | | [B]1.90 | *75.82 | 25.00 | [a] Androcur [GH] | |

**cyproterone acetate 100 mg tablet, 50**

| 8019C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 60.74 | 25.00 | [a] ANTERONE 100 [RW] | [a] Cyproterone Sandoz [HX] |

| 8019C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | [B]1.17 | 61.91 | 25.00 | [a] Androcur-100 [GH] | |

## CYPROTERONE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### cyproterone acetate 50 mg tablet, 50

| 14023C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *134.44 | 25.00 | [a] ANTERONE 50 [RW] | [a] Cyproterone Sandoz [HX] |
| | | | [B]4.00 | *138.44 | 25.00 | [a] Androcur [GH] | |

### cyproterone acetate 100 mg tablet, 50

| 14022B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *107.12 | 25.00 | [a] ANTERONE 100 [RW] | [a] Cyproterone Sandoz [HX] |
| | | | [B]2.34 | *109.46 | 25.00 | [a] Androcur-100 [GH] | |

## DAROLUTAMIDE

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17875***

Castration resistant non-metastatic carcinoma of the prostate

**Clinical criteria:**

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); **OR**
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**Treatment criteria:**

- Patient must be undergoing concurrent treatment with androgen deprivation therapy, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

### darolutamide 300 mg tablet, 112

| 12684N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,575.51 | 25.00 | Nubeqa [BN] |

## DAROLUTAMIDE

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17877***

Metastatic castration sensitive carcinoma of the prostate

**Clinical criteria:**

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); **OR**
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**Treatment criteria:**

- Patient must be undergoing concurrent androgen deprivation therapy, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**darolutamide 300 mg tablet, 112**

| 13769Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,575.51 | 25.00 | Nubeqa [BN] |

## ENZALUTAMIDE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17953***

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); **OR**
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation; **OR**
- Patient must have been receiving PBS-subsidised treatment with abiraterone or abiraterone plus methylprednisolone for castration resistant metastatic prostate cancer prior to being associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**enzalutamide 40 mg capsule, 112**

| 10174L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 3,346.00 | 25.00 | Xtandi [LL] |

## ENZALUTAMIDE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17875***

Castration resistant non-metastatic carcinoma of the prostate

**Clinical criteria:**

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); **OR**
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**Treatment criteria:**

- Patient must be undergoing concurrent treatment with androgen deprivation therapy, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

### enzalutamide 40 mg capsule, 112

| 13118K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,346.00 | 25.00 | Xtandi [LL] |

## ENZALUTAMIDE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***19061***

Hormone sensitive carcinoma of the prostate

**Clinical criteria:**

- The treatment must be for metastatic disease initiated within 6 months of treatment initiation with androgen deprivation therapy unless contraindicated to androgen deprivation therapy; **OR**
- The treatment must be for non-metastatic disease where a baseline PSA doubling time (PSADT) of 9 months or less was observed, and the patient has undergone: (i) radical prostatectomy, (ii) radiation therapy, (iii) neither of the above as both therapies were contraindicated, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (i.e. subsidy cannot occur across different treatment settings); **OR**
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must be undergoing concurrent androgen deprivation therapy unless contraindicated.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

The following applies to patients who are being treated for non-metastatic disease:

(a) patients should cease treatment after 36 weeks if PSA is less than 0.2 ng/mL unless continued treatment is clinically indicated and the patient remains free of metastases;

(b) patients who ceased treatment after meeting the suspension criteria (PSA less than 0.2 ng/mL after 36 weeks) should resume treatment if PSA levels increase to greater than or equal to 2.0 ng/mL for patients who had undergone radical prostatectomy, or greater than or equal to 5.0 ng/mL for those without prior prostatectomy, provided there is no evidence of metastatic disease.

**enzalutamide 40 mg capsule, 112**

| 13353T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 3,346.00 | 25.00 | Xtandi [LL] |

## FLUTAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***5729***
Metastatic (stage D) carcinoma of the prostate
**Clinical criteria:**

- The treatment must be in combination with GnRH (LH-RH) analogue therapy.

**flutamide 250 mg tablet, 100**

| 1417N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 171.60 | 25.00 | Flutamin [AF] |

### *Aromatase inhibitors*

## ANASTROZOLE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.
**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Restricted benefit**
***5522***
Breast cancer
**Clinical criteria:**

- The condition must be hormone receptor positive.

**anastrozole 1 mg tablet, 30**

| 8179L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.77 | 22.31 | [a] Anastrozole GH [GQ] | [a] Anastrozole Sandoz [SZ] |
| | | | | | | [a] ANASTROZOLE-WGR [WG] | [a] APO-Anastrozole [TX] |
| | | | | | | [a] Arianna 1 [AF] | |

## ANASTROZOLE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.
**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Restricted benefit**
***14895***
Breast cancer
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

**anastrozole 1 mg tablet, 30**

| 13858J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *27.18 | 25.00 | [a] Anastrozole GH [GQ] | [a] Anastrozole Sandoz [SZ] |
| | | | | | | [a] ANASTROZOLE-WGR [WG] | [a] APO-Anastrozole [TX] |
| | | | | | | [a] Arianna 1 [AF] | |

## EXEMESTANE

**Restricted benefit**
***17919***
Metastatic (Stage IV) breast cancer
**Clinical criteria:**

- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

**Population criteria:**

- Patient must not be pre-menopausal.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**

- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**exemestane 25 mg tablet, 30**

| 10103R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 51.06 | 25.00 | [a] APO-Exemestane [TX] | [a] Exemestane GH [GQ] |
| | | | | | | [a] Exemestane Sandoz [SZ] | [a] EXEMESTANE-WGR [WG] |
| | | | [B]2.65 | 53.71 | 25.00 | [a] Aromasin [PF] | |

## EXEMESTANE

**Restricted benefit**

***18037***

Metastatic (Stage IV) breast cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

**Population criteria:**

- Patient must not be pre-menopausal.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**exemestane 25 mg tablet, 30**

| 14036R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *87.76 | 25.00 | [a] APO-Exemestane [TX] | [a] Exemestane GH [GQ] |
| | | | | | | [a] Exemestane Sandoz [SZ] | [a] EXEMESTANE-WGR [WG] |
| | | | [B]5.30 | 93.06 | 25.00 | [a] Aromasin [PF] | |

## EXEMESTANE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

**Restricted benefit**

***5522***

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

**exemestane 25 mg tablet, 30**

| 8506Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 51.06 | 25.00 | [a] APO-Exemestane [TX] | [a] Exemestane GH [GQ] |
| | | | | | | [a] Exemestane Sandoz [SZ] | [a] EXEMESTANE-WGR [WG] |
| | | | [B]2.65 | 53.71 | 25.00 | [a] Aromasin [PF] | |

## EXEMESTANE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

**Restricted benefit**

***14895***

Breast cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

**exemestane 25 mg tablet, 30**

| 13857H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *87.76 | 25.00 | [a] APO-Exemestane [TX] | [a] Exemestane GH [GQ] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13857H | | | | | | [a] Exemestane Sandoz [SZ] | [a] EXEMESTANE-WGR [WG] |
| | | | [B]5.30 | 93.06 | 25.00 | [a] Aromasin [PF] | |

## LETROZOLE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Restricted benefit**

***5522***

Breast cancer

**Clinical criteria:**

- The condition must be hormone receptor positive.

### letrozole 2.5 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8245Y NP | 1 | 5 | 0.00 | 22.23 | 23.77 | [a] ARX-LETROZOLE [XT] | [a] Femolet [AF] |
| | | | | | | [a] Gynotril [ZS] | [a] Letrozole GH [HQ] |
| | | | | | | [a] Letrozole Sandoz [SZ] | [a] LETROZOLE-WGR [WG] |
| | | | | | | [a] Pharmacor Letrozole 2.5 [CR] | |
| | | | [B]7.28 | 29.51 | 23.77 | [a] Femara 2.5 mg [NV] | |

## LETROZOLE

**Note** This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note** This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Restricted benefit**

***14895***

Breast cancer

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be hormone receptor positive.

### letrozole 2.5 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13939P NP | 2 | 5 | 0.00 | *30.10 | 25.00 | [a] ARX-LETROZOLE [XT] | [a] Femolet [AF] |
| | | | | | | [a] Gynotril [ZS] | [a] Letrozole GH [HQ] |
| | | | | | | [a] Letrozole Sandoz [SZ] | [a] LETROZOLE-WGR [WG] |
| | | | | | | [a] Pharmacor Letrozole 2.5 [CR] | |
| | | | [B]14.56 | 44.66 | 25.00 | [a] Femara 2.5 mg [NV] | |

## *Other hormone antagonists and related agents*

## ABIRATERONE

**Caution** The bioavailability on a mg to mg basis of abiraterone combination product and abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***17873***

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must be used in combination with a corticosteroid, **AND**
- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); **OR**

- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**abiraterone acetate 250 mg tablet, 120**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2698B NP | 1 | 2 | 0.00 | 681.14 | 25.00 | [a] Abiraterone Dr.Reddy's [RZ] | [a] Abiraterone MedTas [TN] |
| | | | | | | [a] Abiraterone Sandoz [SZ] | [a] Abiraterone-Teva [TB] |
| | | | | | | [a] ABIRATERONE VIATRIS [AF] | [a] ABURA [VM] |
| | | | | | | [a] ARX-ABIRATERONE [XT] | [a] ZYRON [NB] |
| | | | | | | [a] Zytiga [JC] | |

**abiraterone acetate 500 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11206T NP | 1 | 2 | 0.00 | 681.14 | 25.00 | [a] Abiraterone Dr.Reddy's [RZ] | [a] Abiraterone MedTas [TN] |
| | | | | | | [a] Abiraterone Sandoz [SZ] | [a] Abiraterone-Teva [TB] |
| | | | | | | [a] ABIRATERONE VIATRIS [AF] | [a] ABURA [VM] |
| | | | | | | [a] ARX-ABIRATERONE [XT] | [a] ZYRON [NB] |
| | | | | | | [a] Zytiga [JC] | |

## ABIRATERONE (&) METHYLPREDNISOLONE

**Caution** The bioavailability on a mg to mg basis of abiraterone combination product Yonsa MPred to ANDRIGA-10 or abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***17939***

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); **OR**
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [60], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13263C NP | ‡1 | 2 | 0.00 | 682.85 | 25.00 | Yonsa Mpred [RA] |

## ABIRATERONE (&) METHYLPREDNISOLONE

**Caution** The bioavailability on a mg to mg basis of abiraterone combination product Yonsa MPred to ANDRIGA-10 or abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17877***
Metastatic castration sensitive carcinoma of the prostate

**Clinical criteria:**

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); **OR**
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**Treatment criteria:**

- Patient must be undergoing concurrent androgen deprivation therapy, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [30], 1 pack**

| 14078Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 570.97 | 25.00 | Yonsa Mpred [RA] |

## ABIRATERONE (&) PREDNISOLONE

**Caution** The bioavailability on a mg to mg basis of abiraterone combination product Yonsa MPred to ANDRIGA-10 or abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

**Note** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17939***
Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); **OR**
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**abiraterone acetate 500 mg tablet [56] (&) prednisolone 5 mg tablet [56], 112**

| 15209L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | 0.00 | 638.97 | 25.00 | ANDRIGA-10 [KT] |

## DEGARELIX

**Restricted benefit**

***17809***
Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**degarelix 80 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack**

| 2784M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 354.03 | 25.00 | Firmagon 80mg [FP] |

## DEGARELIX

**Note** No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

**Restricted benefit**

***17809***

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**degarelix 120 mg injection [2 vials] (&) inert substance diluent [2 syringes], 1 pack**

| 2785N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 370.16 | 25.00 | Firmagon 120mg [FP] |

# IMMUNOSTIMULANTS

## IMMUNOSTIMULANTS

### *Interferons*

### INTERFERON BETA-1B

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16321***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority Required (STREAMLINED)**

***16297***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**interferon beta-1b 8 million units (250 microgram) injection [15 vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack**

| 8101J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 741.82 | 25.00 | Betaferon [BN] |

### PEGINTERFERON ALFA-2A

**Note** Pharmaceutical benefits that have the brand Pegasys (Ireland) can be substituted for Pegasys in the case of a shortage.

**peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 11416W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 916.84 | 25.00 | [a] Pegasys [XO] |

**peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 15045W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 1,296.83 | 25.00 | [a] Pegasys (Ireland) [XO] |

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 11037X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 1,060.29 | 25.00 | [a] Pegasys [XO] |

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

| 14992C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 1,353.48 | 25.00 | [a] Pegasys (Ireland) [XO] |

## PEGINTERFERON BETA-1A

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***16321***
Multiple sclerosis
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL pen device] (&) peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL pen device], 1 pack**

| 10218T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 617.69 | 25.00 | Plegridy [BD] |

**peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL pen devices**

| 10212L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 4 | 0.00 | 617.69 | 25.00 | Plegridy [BD] |

## PEGINTERFERON BETA-1A

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***16297***
Multiple sclerosis
Treatment Phase: Continuing treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL pen devices**

| 10220X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 617.69 | 25.00 | Plegridy [BD] |

### *Other immunostimulants*

## GLATIRAMER ACETATE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***16321***
Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority Required (STREAMLINED)**

***16297***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10416F NP | 1 | 5 | 0.00 | 547.80 | 25.00 | [a] Copaxone [TB] | [a] Glatira [JU] |

## MYCOBACTERIUM BOVIS BCG DANISH STRAIN

**Restricted benefit**

***5540***

Primary and relapsing superficial urothelial carcinoma of the bladder

**Mycobacterium bovis BCG Danish strain 30 mg injection, 4 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12931N | ‡3 | 1 | 0.00 | *1,816.35 | 25.00 | VesiCulture [LM] |

## MYCOBACTERIUM BOVIS BCG TICE STRAIN

**Restricted benefit**

***5540***

Primary and relapsing superficial urothelial carcinoma of the bladder

**Mycobacterium bovis BCG Tice strain 500 million CFU injection, 3 vials**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1131M | 1 | 1 | 0.00 | 446.86 | 25.00 | OncoTICE [MK] |

# IMMUNOSUPPRESSANTS

## IMMUNOSUPPRESSANTS

### *Selective immunosuppressants*

## ABATACEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the

total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***14604***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

13726K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 928.93 | 25.00 | Orencia [BQ] |

**abatacept 125 mg/mL injection, 4 x 1 mL pen devices**

13727L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 928.93 | 25.00 | Orencia ClickJect [BQ] |

## ABATACEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18560***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***14507***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

| 1221G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 928.93 | 25.00 | Orencia [BQ] |

**abatacept 125 mg/mL injection, 4 x 1 mL pen devices**

| 11684Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 928.93 | 25.00 | Orencia ClickJect [BQ] |

## ABATACEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where

prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18633***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18635***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight

with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18596***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of

biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18584***

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### abatacept 125 mg/mL injection, 4 x 1 mL syringes

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1220F | 1 | 3 | 0.00 | 928.93 | 25.00 | Orencia [BQ] |

### abatacept 125 mg/mL injection, 4 x 1 mL pen devices

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11693K | 1 | 3 | 0.00 | 928.93 | 25.00 | Orencia ClickJect [BQ] |

## APREMILAST

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17351***

Severe chronic plaque psoriasis

**Clinical criteria:**

- Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; **OR**
- Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; **OR**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate, **AND**
- The condition must have caused significant interference with quality of life, **AND**
- Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) deucravacitinib.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; **OR**
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; **OR**
- Must be treated by a prescriber who is not any of the above, but where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types.

**Population criteria:**

- Patient must be at least 18 years of age.

For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

**apremilast 10 mg tablet [4] (&) apremilast 20 mg tablet [4] (&) apremilast 30 mg tablet [19], 27**

| 12218C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 253.76 | 25.00 | Otezla [AN] |

**apremilast 30 mg tablet, 56**

| 12223H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 604.42 | 25.00 | Otezla [AN] |

## CLADRIBINE

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16345***

Relapsing remitting multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed by a neurologist, **AND**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

The prescriber should write authority prescriptions for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.

**Authority Required (STREAMLINED)**

***16299***

Relapsing remitting multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate, this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

The prescriber should request authority approval for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.

**cladribine 10 mg tablet, 1**

| 11603Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 1,234.83 | 25.00 | [a] CLADRITAB [JG] | [a] Mavenclad [SG] |

**cladribine 10 mg tablet, 4**

| 11604R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *9,308.26 | 25.00 | [a] CLADRITAB [JG] | [a] Mavenclad [SG] |

**cladribine 10 mg tablet, 6**

| 11611D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 6,997.04 | 25.00 | [a] CLADRITAB [JG] | [a] Mavenclad [SG] |

## MYCOPHENOLATE

**Caution** Where prescribed by a non-specialist prescriber, consult with a specialist medical practitioner on matters of diagnosis, choice of immunosuppressant and monitoring of immunosuppression in the patient.

**mycophenolate 180 mg enteric tablet, 120**

| 2150E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 88.35 | 25.00 | [a] Mycophenolic Acid ARX [XT] | [a] Myfortic [NV] |

**mycophenolate mofetil 250 mg capsule, 100**

| 8649F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *74.46 | 25.00 | [a] APO-Mycophenolate [TX] | [a] Mycophenolate Sandoz [SZ] |
| | | | | | | [a] Pharmacor Mycophenolate 250 [CR] | |

**mycophenolate 360 mg enteric tablet, 120**

| 2193K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 152.35 | 25.00 | [a] Mycophenolic Acid ARX [XT] | [a] MYCOTEX [CR] |
| | | | | | | [a] Myfortic [NV] | |

**mycophenolate mofetil 500 mg tablet, 50**

| 8650G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *74.37 | 25.00 | [a] ARX-MYCOPHENOLATE [XT] | [a] Ceptolate [AF] |
| | | | | | | [a] Mycophenolate GH [GQ] | [a] Mycophenolate Sandoz [SZ] |
| | | | | | | [a] Pharmacor Mycophenolate 500 [CR] | |

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

| 8651H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 216.42 | 25.00 | [a] CellCept [RO] | [a] Pharmacor Mycophenolate [CR] |

## MYCOPHENOLATE

**Caution** Where prescribed by a non-specialist prescriber, consult with a specialist medical practitioner on matters of diagnosis, choice of immunosuppressant and monitoring of immunosuppression in the patient.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**mycophenolate 180 mg enteric tablet, 120**

| 13856G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *164.74 | 25.00 | [a] Mycophenolic Acid ARX [XT] | [a] Myfortic [NV] |

**mycophenolate mofetil 250 mg capsule, 100**

| 13884R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | 0.00 | *135.54 | 25.00 | [a] APO-Mycophenolate [TX] | [a] Mycophenolate Sandoz [SZ] |
| | | | | | | [a] Pharmacor Mycophenolate 250 [CR] | |

**mycophenolate 360 mg enteric tablet, 120**

| 13938N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *295.34 | 25.00 | [a] Mycophenolic Acid ARX [XT] | [a] MYCOTEX [CR] |
| | | | | | | [a] Myfortic [NV] | |

**mycophenolate mofetil 500 mg tablet, 50**

| 14000W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 6 | 5 | 0.00 | *135.36 | 25.00 | [a] ARX-MYCOPHENOLATE [XT] | [a] Ceptolate [AF] |
| | | | | | | [a] Mycophenolate GH [GQ] | [a] Mycophenolate Sandoz [SZ] |
| | | | | | | [a] Pharmacor Mycophenolate 500 [CR] | |

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

| 14071N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *420.23 | 25.00 | [a] CellCept [RO] | [a] Pharmacor Mycophenolate [CR] |

## *Tumor necrosis factor alpha (TNF-alpha) inhibitors*

### ADALIMUMAB

**Note** The assessment for Juvenile Spondyloarthritis Disease Activity Index score is available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4245319/table/T2/.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17715***

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a diagnosis of enthesitis/spondylitis related juvenile idiopathic arthritis defined by at least one of the following: (i) peripheral arthritis and enthesitis, (ii) inflammatory sacroiliitis on Magnetic Resonance Imaging (MRI) plus at least 3 months of inflammatory back pain, (iii) arthritis or enthesitis plus at least 2 of: (a) sacroiliac joint tenderness, (b) inflammatory back pain, (c) presence of HLA-B27 antigen, (d) acute (symptomatic) anterior uveitis, (e) history of spondyloarthritis in a first-degree relative, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have had a break in treatment of at least 2 years from the most recently prescribed PBS-subsidised biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response for axial disease (sacroiliitis and/or spondylitis), following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) whilst completing an appropriate exercise program, for a total period of 3 months; **OR**
- Patient must have failed to achieve an adequate response for peripheral disease (arthritis and/or enthesitis) following treatment with at least 2 NSAIDs, and either: (i) methotrexate at a dose of 15 mg per square metre (maximum 20 mg) weekly, (ii) sulfasalazine at a dose of 20 mg/kg (maximum 1 g) twice daily, whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Population criteria:**

- Patient must be under 18 years of age.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If treatment with methotrexate, sulfasalazine or NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to methotrexate, sulfasalazine or NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Juvenile Spondyloarthritis Disease Activity Index score greater than 2; or

(b) persistent symptoms of axial spondylitis or sacroiliitis with prior confirmatory Magnetic Resonance Imaging (MRI) assessed by a clinician experienced with juvenile spondyloarthropathy.

The following must be provided at the time of application and documented in the patient's medical records:

(1) details of prior treatment including dose and duration of treatment; and

(i) if applicable, the baseline Juvenile Spondyloarthritis Disease Activity Index score; or

(ii) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) of the MRI demonstrating inflammatory spondylitis or sacroiliitis; or

(iii) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) demonstrating the presence of HLA-B27.

The Juvenile Spondyloarthritis Disease Activity Index score must be assessed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority Required**

***17731***

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Initial treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 15148G | 1 | 3 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15572N | 2 | 3 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15155P | 2 | 3 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17679***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; **OR**
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.

The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority Required**

***17587***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority Required**

***17617***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12454L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *1,299.09 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12356H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *1,299.09 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

**Initial 1 -** use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

**Initial 2 -** use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

**Initial 3 -** use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

**Continuing treatment -** use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

**Baseline measurements to determine response -** a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18968***

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must not have achieved an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy with a thiopurine at a clinically optimised dose, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented contraindication to each of prednisolone (or equivalent), a thiopurine, and methotrexate; **OR**
- Patient must have features of high-risk or complicated Crohn disease defined as those with any of the following: (i) perianal disease, (ii) stricturing or penetrating behaviour, (iii) severe delayed growth (growth velocity at least 2 standard deviations below the mean for age and sex, or a drop of at least 1 major centile band), **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; **OR**
- Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) current PCDAI score and the date of assessment; or

(c) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18966***

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must not have previously received this drug for this condition in this treatment cycle; **OR**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response; **OR**
- Patient must have: (i) received this drug in this treatment cycle, (ii) not demonstrated/maintained an adequate response to this drug once in this treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the PCDAI score and the date of assessment; or

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' clinical and treatment criteria when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18967***

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

### adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12409D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *2,042.73 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

### adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12426B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *2,042.73 | 25.00 | [a] Amgevita [AN] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***14670***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and

(iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

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**Authority Required**

***14673***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***14672***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13763J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 13744J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***14670***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and

(iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Authority Required**

***14673***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***14672***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13764K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

13754X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***13650***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16414***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***13694***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9064***

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12378L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9033K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***14670***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by

a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14655***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14662***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing

Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**

- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***12174***

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12442W | 1 | 3 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9077R | 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***13650***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16414***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***13694***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9064***

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12362P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9101B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***14670***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**

- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14655***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**

- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14662***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***12174***

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12376J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9103D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Authority Required**

***18813***

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**

- Patient must not have achieved an adequate response to a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of not achieving an adequate response to prior systemic therapy; **OR**
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below; **OR**
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(c) if applicable, details of intestinal inflammation marker/s; and

(d) if applicable, the CDAI score and the date of assessment; and

(e) the date of the most recent clinical assessment.

Evidence of not achieving an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18814***

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***18815***

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 while off treatment with targeted therapy; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; and evidence of flared disease while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and evidence of flared disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***18767***

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, or Continuing treatment), **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12451H | 1 | 2 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12453K | 3 | 0 | 0.00 | 1,468.65 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9188N | 1 | 2 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12387Y | 3 | 0 | 0.00 | 1,299.09 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an

adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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**Authority Required**

***18813***

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must not have achieved an adequate response to a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of not achieving an adequate response to prior systemic therapy; **OR**
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below; **OR**
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(c) if applicable, details of intestinal inflammation marker/s; and

(d) if applicable, the CDAI score and the date of assessment; and

(e) the date of the most recent clinical assessment.

Evidence of not achieving an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18814***

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***18815***

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 while off treatment with targeted therapy; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; and evidence of flared disease while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and evidence of flared disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion

must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***18767***

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, or Continuing treatment), **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 12345R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 12433J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | 1,299.09 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 9190Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 12402R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | 1,299.09 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

**Initial 2** - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

**(i) Discharge**

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

**(ii) Pain**

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

**(iii) Degree of induration**

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***19106***

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**

- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition must be provided by the prescriber at the time of application and documented in the patient's medical records.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

**Authority Required**

***19115***

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition; and

(b) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The application must also provide details of the baseline scores of the prior eligibility requirements, including the number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

**Authority Required**

***19149***

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1 or Initial 2), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12380N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *1,468.65 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |

| 12380N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 12397L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | *495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 8963R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 12331B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | 1,299.09 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

**Initial 2** - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

**(i) Discharge**

- 0 - no discharge

- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

**(ii) Pain**

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

**(iii) Degree of induration**

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***19106***

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition must be provided by the prescriber at the time of application and documented in the patient's medical records.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

**Authority Required**

***19115***

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition; and

(b) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The application must also provide details of the baseline scores of the prior eligibility requirements, including the number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

**Authority Required**

***19149***

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1 or Initial 2), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 12340L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 12381P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | 1,299.09 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 8965W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 12386X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | 1,299.09 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

**Initial 1 -** use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

**Initial 2 -** use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

**Initial 3 -** use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

**Continuing treatment -** use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

**Baseline measurements to determine response -** a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18968***

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must not have achieved an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy with a thiopurine at a clinically optimised dose, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented contraindication to each of prednisolone (or equivalent), a thiopurine, and methotrexate; **OR**
- Patient must have features of high-risk or complicated Crohn disease defined as those with any of the following: (i) perianal disease, (ii) stricturing or penetrating behaviour, (iii) severe delayed growth (growth velocity at least 2 standard deviations below the mean for age and sex, or a drop of at least 1 major centile band), **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; **OR**
- Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) current PCDAI score and the date of assessment; or

(c) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18966***

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must not have previously received this drug for this condition in this treatment cycle; **OR**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response; **OR**
- Patient must have: (i) received this drug in this treatment cycle, (ii) not demonstrated/maintained an adequate response to this drug once in this treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**

- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the PCDAI score and the date of assessment; or

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' clinical and treatment criteria when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18967***

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12373F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 12432H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | 1,299.09 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 10413C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 12388B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | 1,299.09 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

**Initial 1 -** use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

**Initial 2 -** use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

**Initial 3 -** use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

**Continuing treatment -** use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

**Baseline measurements to determine response -** a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18968***

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must not have achieved an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy with a thiopurine at a clinically optimised dose, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented contraindication to each of prednisolone (or equivalent), a thiopurine, and methotrexate; **OR**
- Patient must have features of high-risk or complicated Crohn disease defined as those with any of the following: (i) perianal disease, (ii) stricturing or penetrating behaviour, (iii) severe delayed growth (growth velocity at least 2 standard deviations below the mean for age and sex, or a drop of at least 1 major centile band), **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; **OR**
- Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) current PCDAI score and the date of assessment; or

(c) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18966***

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must not have previously received this drug for this condition in this treatment cycle; **OR**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response; **OR**
- Patient must have: (i) received this drug in this treatment cycle, (ii) not demonstrated/maintained an adequate response to this drug once in this treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the PCDAI score and the date of assessment; or

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' clinical and treatment criteria when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18967***

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 12338J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 12455M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | 1,468.65 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 10419J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 12416L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | 1,299.09 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***14496***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of results;

(b) details of prior treatment, including dose and date/duration of treatment.

(c) If applicable, details of any contraindications/intolerances.

(d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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**Authority Required**

***14590***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Authority Required**

***14568***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of result;

(b) the most recent biological agent and the date of the last continuing prescription.

(c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13691N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

13692P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***14496***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of results;

(b) details of prior treatment, including dose and date/duration of treatment.

(c) If applicable, details of any contraindications/intolerances.

(d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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**Authority Required**

***14590***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Authority Required**

***14568***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of result;

(b) the most recent biological agent and the date of the last continuing prescription.

(c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 13704G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 13722F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18534***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated

according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18562***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18604***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18584***

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12400P | 1 | 3 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8737W | 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the

necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18534***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18562***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18604***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18584***

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 12429E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 9099X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at

the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17031***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17032***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; **OR**
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; **OR**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17077***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16982***

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12359L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12382Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 0 | 0.00 | 1,468.65 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

10944B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12333D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 0 | 0.00 | 1,299.09 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17031***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**

- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17032***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; **OR**
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; **OR**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17077***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16982***

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12347W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *1,299.09 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12412G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | 0.00 | *439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 10955N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 12370C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | 1,299.09 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

**Initial 1 -** use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

**Initial 2 -** use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

**Initial 3 -** use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

**Continuing treatment -** use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

**Baseline measurements to determine response -** a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***18968***

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must not have achieved an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy with a thiopurine at a clinically optimised dose, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented contraindication to each of prednisolone (or equivalent), a thiopurine, and methotrexate; **OR**
- Patient must have features of high-risk or complicated Crohn disease defined as those with any of the following: (i) perianal disease, (ii) stricturing or penetrating behaviour, (iii) severe delayed growth (growth velocity at least 2 standard deviations below the mean for age and sex, or a drop of at least 1 major centile band), **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; **OR**
- Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) current PCDAI score and the date of assessment; or

(c) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18966***

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must not have previously received this drug for this condition in this treatment cycle; **OR**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response; **OR**
- Patient must have: (i) received this drug in this treatment cycle, (ii) not demonstrated/maintained an adequate response to this drug once in this treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the PCDAI score and the date of assessment; or

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' clinical and treatment criteria when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18967***

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

12407B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe**

15591N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12332C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17031***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17032***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; **OR**
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; **OR**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***17077***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16982***

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

12371D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe**

15584F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12350B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18544***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18587***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18545***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18535***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18540***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18543***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12394H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 687.15 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12447D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 687.15 | 25.00 | [a] Amgevita [AN] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17043***

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:
(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.
A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:
(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;
(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);
(iii) the PASI score that followed each prior therapy trialled;
(iv) the date the PASI scores were determined.
Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority Required**

***17005***

Severe chronic plaque psoriasis
Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:
(1) details of the proposed prescription(s); and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.
Response to preceding supply:
An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.
Change in therapy:
If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:
(i) there is an absence of an adequate response to that treatment; or
(ii) there was an intolerance to that treatment; or
(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above
Recommencing therapy:
If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:
(i) an absence of an adequate response; or
(ii) an intolerance to that treatment; or
(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17046***

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; **OR**
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; **OR**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17042***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2 or 3 treatment (Whole body, or, face/hand/foot)

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of 17 weeks of treatment available under any of the initial treatment phases.

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 3 doses available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***17044***

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

**Clinical criteria:**

- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***17045***

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.

Response to preceding supply:

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

(i) an absence of an adequate response; or

(ii) an intolerance to that treatment; or

(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 15031D | 1 | 4 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14985Q | 1 | 4 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17043***

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) the PASI score that followed each prior therapy trialled;

(iv) the date the PASI scores were determined.

Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17005***

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.

Response to preceding supply:

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

(i) an absence of an adequate response; or

(ii) an intolerance to that treatment; or

(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17046***

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; **OR**
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**

- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; **OR**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17042***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2 or 3 treatment (Whole body, or, face/hand/foot)

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of 17 weeks of treatment available under any of the initial treatment phases.

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 3 doses available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***17044***

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

**Clinical criteria:**

- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17045***

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.

Response to preceding supply:

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

(i) an absence of an adequate response; or

(ii) an intolerance to that treatment; or

(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 15010B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 4 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 15020M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 4 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17043***

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) the PASI score that followed each prior therapy trialled;

(iv) the date the PASI scores were determined.

Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17005***

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.

Response to preceding supply:

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

(i) an absence of an adequate response; or

(ii) an intolerance to that treatment; or

(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17046***

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; **OR**
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; **OR**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17042***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2 or 3 treatment (Whole body, or, face/hand/foot)

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of 17 weeks of treatment available under any of the initial treatment phases.

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 3 doses available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***17044***

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

**Clinical criteria:**

- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17045***

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- Patient must not receive more than 17 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.

Response to preceding supply:

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

(i) an absence of an adequate response; or

(ii) an intolerance to that treatment; or

(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

| 14976F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 4 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe**

| 15573P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 4 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

| 14975E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 4 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***18544***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***18587***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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HOBART TAS 7001

**Authority Required**

***18545***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18535***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18540***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18543***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18590***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12421R | 1 | 4 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 9425C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 4 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18544***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18587***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18545***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18535***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18540***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18543***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Prescribing the 80 mg presentation:**

Two completed authority prescriptions may be submitted with every initial application for this biological medicine. One prescription for an induction dose of 80 mg and no repeats and the second prescription for 2 doses of 40 mg and 3 repeats.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18590***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12342N | 1 | 4 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9426D | 1 | 4 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15445***

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**

- The treatment must not exceed 24 weeks under this restriction per authority application.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

14234E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

14262P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required**

***15473***

Vision threatening non-infectious uveitis

Treatment Phase: Balance of Supply

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition to complete one of the following: (i) 25 weeks for initial treatment; (ii) 25 weeks for recommencement treatment; (iii) 24 weeks for continuing treatment; (iv) 24 weeks for transitioning from non-PBS to PBS-subsidised treatment.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

14242N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

14263Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15445***

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 14629Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 14243P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required**

***15473***

Vision threatening non-infectious uveitis

Treatment Phase: Balance of Supply

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition to complete one of the following: (i) 25 weeks for initial treatment; (ii) 25 weeks for recommencement treatment; (iii) 24 weeks for continuing treatment; (iv) 24 weeks for transitioning from non-PBS to PBS-subsidised treatment.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 14586Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 14283R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***11529***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

### adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

14587R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *1,364.94 | 25.00 | [a] Amgevita [AN] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

### adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

14622N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *1,364.94 | 25.00 | Yuflyma [EW] |

## ADALIMUMAB

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15445***

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

### Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15557T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

## ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

**Initial 1 -** use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

**Initial 2 -** use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

**Initial 3 -** use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

**Continuing treatment -** use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

**Baseline measurements to determine response -** a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Authority Required**

***18989***

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1, 2 or 3), **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12379M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

10399H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

**Initial 1 -** use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

**Initial 2 -** use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

**Initial 3 -** use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

**Continuing treatment -** use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

**Baseline measurements to determine response -** a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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**Authority Required**

***18989***

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1, 2 or 3), **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

| 12411F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

| 10400J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***16991***

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13213K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12325Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***11529***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 13221W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *869.18 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 12330Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *869.18 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16991***

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13211H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12334E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***11604***

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13209F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12365T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |

| 12365T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***15788***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years), or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.

### adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12395J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *1,364.94 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

### adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12449F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *1,364.94 | 25.00 | [a] Amgevita [AN] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***11604***

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13223Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12401Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***11523***

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 13214L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 12415K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***11523***

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13216N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12438P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15446***

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrated or sustained an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

14221L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

14261N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 14261N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required**

***15473***

Vision threatening non-infectious uveitis

Treatment Phase: Balance of Supply

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition to complete one of the following: (i) 25 weeks for initial treatment; (ii) 25 weeks for recommencement treatment; (iii) 24 weeks for continuing treatment; (iv) 24 weeks for transitioning from non-PBS to PBS-subsidised treatment.

### adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 14245R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| | 1 | 0 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

### Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

| | | | | | | |
|---|---|---|---|---|---|---|
| 15563D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| | 2 | 0 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

### adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

| | | | | | | |
|---|---|---|---|---|---|---|
| 14749G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| | 2 | 0 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15446***

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrated or sustained an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 14591Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 14251C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15445***

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

| 15539W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 606.96 | 25.00 | [a] Yuflyma [EW] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

| 14772L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17736***

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response is defined as an improvement from baseline in the Juvenile Spondyloarthritis Disease Activity Index score by at least 30% or an improvement in the persistent symptoms of axial spondylitis or sacroiliitis.

If a patient fails to demonstrate a response to treatment with this drug, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 2 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed, and the date of the first application submitted for approval.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

15153M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

15160X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17736***

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response is defined as an improvement from baseline in the Juvenile Spondyloarthritis Disease Activity Index score by at least 30% or an improvement in the persistent symptoms of axial spondylitis or sacroiliitis.

If a patient fails to demonstrate a response to treatment with this drug, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 2 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed, and the date of the first application submitted for approval.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

15189K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

15162B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the

patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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**Authority Required**

***18552***

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18594***

Severe active juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***18631***

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient doses for up to 24 weeks treatment. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12399N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

5283C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

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**Authority Required**

***18552***

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***18594***

Severe active juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***18631***

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient doses for up to 24 weeks treatment. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12425Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

5284D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***18771***

Severe Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12410E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9189P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***18771***

Severe Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the

need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 12389C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 9191R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16991***

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

| 14996G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe**

| 15575R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

| 12351C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***18721***

Severe Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13225C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12352D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

**Initial 1 -** use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

**Initial 2 -** use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

**Initial 3 -** use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

**Continuing treatment -** use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

**Baseline measurements to determine response -** a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Authority Required**

***18989***

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1, 2 or 3), **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

### adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12423W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

### Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe

15590M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 0 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

### adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12354F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 0 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15788***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years), or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12383R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *869.18 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12385W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *869.18 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

**Initial 1 -** use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

**Initial 2 -** use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

**Initial 3 -** use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

**Continuing treatment -** use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

**Baseline measurements to determine response -** a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***18991***

Severe Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**

- Patient must have both: (i) a total PCDAI score of 40 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; **OR**
- Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition under this treatment phase. Patients may re-trial treatment with this drug under the 'Initial 2' treatment phase if eligible. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13224B | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12420Q | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

**Initial 1 -** use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

**Initial 2 -** use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

**Initial 3 -** use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

**Continuing treatment -** use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

**Baseline measurements to determine response -** a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***18991***

Severe Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have both: (i) a total PCDAI score of 40 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; **OR**
- Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition under this treatment phase. Patients may re-trial treatment with this drug under the 'Initial 2' treatment phase if eligible. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 13218Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 12434K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***18721***

Severe Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 13219R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 12437N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15446***

Vision threatening non-infectious uveitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrated or sustained an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 weeks under this restriction per authority application.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

| 14275H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe**

| 15583E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

| 14747E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note** The assessment for Juvenile Spondyloarthritis Disease Activity Index score is available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4245319/table/T2/.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17730***

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2026, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, a diagnosis of enthesitis/spondylitis related juvenile idiopathic arthritis defined by at least one of the following: (i) peripheral arthritis and enthesitis, (ii) inflammatory sacroiliitis on Magnetic Resonance Imaging (MRI) plus at least 3 months of inflammatory back pain, (iii) arthritis or enthesitis plus at least 2 of: (a) sacroiliac joint tenderness, (b) inflammatory back pain, (c) presence of HLA-B27 antigen, (d) acute (symptomatic) anterior uveitis, (e) history of spondyloarthritis in a first-degree relative, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, failed to achieve an adequate response for axial disease (sacroiliitis and/or spondylitis), following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) whilst completing an appropriate exercise program, for a total period of 3 months; **OR**
- Patient must have, prior to initiating treatment with this drug for this condition, failed to achieve an adequate response for peripheral disease (arthritis and/or enthesitis) following treatment with at least 2 NSAIDs, and either: (i) methotrexate at a dose of 15 mg per square metre (maximum 20 mg) weekly, (ii) sulfasalazine at a dose of 20 mg/kg (maximum 1 g) twice daily, whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Population criteria:**

- Patient must be under 18 years of age, prior to commencement of this drug for this condition.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If treatment with methotrexate, sulfasalazine or NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to methotrexate, sulfasalazine or NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Juvenile Spondyloarthritis Disease Activity Index score greater than 2; or

(b) persistent symptoms of axial spondylitis or sacroiliitis with prior confirmatory Magnetic Resonance Imaging (MRI) assessed by a clinician experienced with juvenile spondyloarthropathy.

The following must be provided at the time of application and documented in the patient's medical records:

(1) details of prior treatment including dose and duration of treatment; and

(i) if applicable, a baseline Juvenile Spondyloarthritis Disease Activity Index score; or

(ii) if applicable, the current Juvenile Spondyloarthritis Disease Activity Index score; or

(iii) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) of the MRI demonstrating inflammatory spondylitis or sacroiliitis; or

(iv) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) demonstrating the presence of HLA-B27.

The Juvenile Spondyloarthritis Disease Activity Index score must be assessed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

An adequate response is defined as an improvement from baseline in the Juvenile Spondyloarthritis Disease Activity Index score by at least 30% or an improvement in the persistent symptoms of axial spondylitis or sacroiliitis.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 15170K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 15137Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note** The assessment for Juvenile Spondyloarthritis Disease Activity Index score is available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4245319/table/T2/.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17730***

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2026, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, a diagnosis of enthesitis/spondylitis related juvenile idiopathic arthritis defined by at least one of the following: (i) peripheral arthritis and enthesitis, (ii) inflammatory sacroiliitis on Magnetic Resonance Imaging (MRI) plus at least 3 months of inflammatory back pain, (iii) arthritis or enthesitis plus at least 2 of: (a) sacroiliac joint tenderness, (b) inflammatory back pain, (c) presence of HLA-B27 antigen, (d) acute (symptomatic) anterior uveitis, (e) history of spondyloarthritis in a first-degree relative, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, failed to achieve an adequate response for axial disease (sacroiliitis and/or spondylitis), following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) whilst completing an appropriate exercise program, for a total period of 3 months; **OR**
- Patient must have, prior to initiating treatment with this drug for this condition, failed to achieve an adequate response for peripheral disease (arthritis and/or enthesitis) following treatment with at least 2 NSAIDs, and either: (i) methotrexate at a dose of 15 mg per square metre (maximum 20 mg) weekly, (ii) sulfasalazine at a dose of 20 mg/kg (maximum 1 g) twice daily, whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Population criteria:**

- Patient must be under 18 years of age, prior to commencement of this drug for this condition.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If treatment with methotrexate, sulfasalazine or NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to methotrexate, sulfasalazine or NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Juvenile Spondyloarthritis Disease Activity Index score greater than 2; or

(b) persistent symptoms of axial spondylitis or sacroiliitis with prior confirmatory Magnetic Resonance Imaging (MRI) assessed by a clinician experienced with juvenile spondyloarthropathy.

The following must be provided at the time of application and documented in the patient's medical records:

(1) details of prior treatment including dose and duration of treatment; and

(i) if applicable, a baseline Juvenile Spondyloarthritis Disease Activity Index score; or

(ii) if applicable, the current Juvenile Spondyloarthritis Disease Activity Index score; or

(iii) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) of the MRI demonstrating inflammatory spondylitis or sacroiliitis; or

(iv) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) demonstrating the presence of HLA-B27.

The Juvenile Spondyloarthritis Disease Activity Index score must be assessed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

An adequate response is defined as an improvement from baseline in the Juvenile Spondyloarthritis Disease Activity Index score by at least 30% or an improvement in the persistent symptoms of axial spondylitis or sacroiliitis.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

| 15159W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

| 15147F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17736***

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response is defined as an improvement from baseline in the Juvenile Spondyloarthritis Disease Activity Index score by at least 30% or an improvement in the persistent symptoms of axial spondylitis or sacroiliitis.

If a patient fails to demonstrate a response to treatment with this drug, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 2 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed, and the date of the first application submitted for approval.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 15149H | 1 | 5 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15566G | 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15180Y | 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***11635***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required (STREAMLINED)**

***11606***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13217P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12366W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***11635***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required (STREAMLINED)**

***11606***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13215M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12403T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17620***

Moderate to severe hidradenitis suppurativa

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority Required**

***17663***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12408C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *1,364.94 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12448E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *1,364.94 | 25.00 | [a] Amgevita [AN] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

## ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***14499***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13222X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12326R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***14499***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 13227E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 12329X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

**Initial 2** - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

**(i) Discharge**

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

**(ii) Pain**

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

**(iii) Degree of induration**

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***19174***

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 13230H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 12353E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

**Initial 2** - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

**(i) Discharge**

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

**(ii) Pain**

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort

- 4 - severe pain

**(iii) Degree of induration**

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***19174***

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13220T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12367X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

**Initial 1 -** use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

**Initial 2 -** use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

**Initial 3 -** use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

**Continuing treatment -** use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

**Baseline measurements to determine response -** a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***18991***

Severe Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have both: (i) a total PCDAI score of 40 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; **OR**
- Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**

- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition under this treatment phase. Patients may re-trial treatment with this drug under the 'Initial 2' treatment phase if eligible. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14995F | 1 | 5 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15567H | 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12436M | 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***14567***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13703F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

13686H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***14567***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13732R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

13721E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note** The assessment for Juvenile Spondyloarthritis Disease Activity Index score is available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4245319/table/T2/.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17730***

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2026, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, a diagnosis of enthesitis/spondylitis related juvenile idiopathic arthritis defined by at least one of the following: (i) peripheral arthritis and enthesitis, (ii) inflammatory sacroiliitis on Magnetic Resonance Imaging (MRI) plus at least 3 months of inflammatory back pain, (iii) arthritis or enthesitis plus at least 2 of: (a) sacroiliac joint tenderness, (b) inflammatory back pain, (c) presence of HLA-B27 antigen, (d) acute (symptomatic) anterior uveitis, (e) history of spondyloarthritis in a first-degree relative, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, failed to achieve an adequate response for axial disease (sacroiliitis and/or spondylitis), following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) whilst completing an appropriate exercise program, for a total period of 3 months; **OR**
- Patient must have, prior to initiating treatment with this drug for this condition, failed to achieve an adequate response for peripheral disease (arthritis and/or enthesitis) following treatment with at least 2 NSAIDs, and either: (i) methotrexate at a dose of 15 mg per square metre (maximum 20 mg) weekly, (ii) sulfasalazine at a dose of 20 mg/kg (maximum 1 g) twice daily, whilst completing an appropriate exercise program, for a total period of 3 months, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Population criteria:**

- Patient must be under 18 years of age, prior to commencement of this drug for this condition.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If treatment with methotrexate, sulfasalazine or NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to methotrexate, sulfasalazine or NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Juvenile Spondyloarthritis Disease Activity Index score greater than 2; or

(b) persistent symptoms of axial spondylitis or sacroiliitis with prior confirmatory Magnetic Resonance Imaging (MRI) assessed by a clinician experienced with juvenile spondyloarthropathy.

The following must be provided at the time of application and documented in the patient's medical records:

(1) details of prior treatment including dose and duration of treatment; and

(i) if applicable, a baseline Juvenile Spondyloarthritis Disease Activity Index score; or

(ii) if applicable, the current Juvenile Spondyloarthritis Disease Activity Index score; or

(iii) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) of the MRI demonstrating inflammatory spondylitis or sacroiliitis; or

(iv) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) demonstrating the presence of HLA-B27.

The Juvenile Spondyloarthritis Disease Activity Index score must be assessed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

An adequate response is defined as an improvement from baseline in the Juvenile Spondyloarthritis Disease Activity Index score by at least 30% or an improvement in the persistent symptoms of axial spondylitis or sacroiliitis.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

15190L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe**

15548H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

15172M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is

based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16725***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***14507***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12430F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

8741C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16725***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***14507***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12390D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9100Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16993***

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6

to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction for patients who:

(i) received fewer than 5 repeats at the time of application; and/or

(ii) required changes to their dosing regimen during this treatment phase.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Authority Required**

***17030***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12391E | 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10960W | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16993***

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction for patients who:

(i) received fewer than 5 repeats at the time of application; and/or

(ii) required changes to their dosing regimen during this treatment phase.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Authority Required**

***17030***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 12358K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 10961X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***14683***

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required (STREAMLINED)**

***14701***

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13208E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12327T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot

change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***14683***

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required (STREAMLINED)**

***14701***

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13226D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12328W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements

any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17620***

Moderate to severe hidradenitis suppurativa

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority Required**

***17663***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12414J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *869.18 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12369B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *869.18 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15474***

Vision threatening non-infectious uveitis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist, **AND**
- Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent; **OR**
- Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy; **OR**
- Patient must have failed to achieve an adequate response to at least one immunosuppressive agent in patients for whom corticosteroids are not clinically appropriate; **OR**
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy, **AND**
- The treatment must not exceed 25 weeks under this restriction.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Vision threatening disease is defined as at least 1 of the following:

(a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent;

(b) A 2-step increase in anterior chamber cells or vitreous haze;

(c) New retinal vasculitis;

(d) New retinal or choroidal lesions;

(e) Other signs of disease progression including visual field changes or electroretinogram changes

A failure to achieve an adequate response is defined as failure to meet one or more of the below criteria:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

Details of prior immunomodulatory agent and corticosteroid treatment, or details of contraindications or developed intolerances necessitating treatment withdrawal, must be documented in the patient's medical record.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include details of vision threatening disease.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***15489***

Vision threatening non-infectious uveitis

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have a documented history of non-infectious uveitis that is vision threatening, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment prior to having a break in therapy with this drug for this condition, **AND**
- The treatment must not exceed 25 weeks under this restriction.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

14628X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 6 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

14222M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 6 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***15474***

Vision threatening non-infectious uveitis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist, **AND**
- Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent; **OR**
- Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy; **OR**
- Patient must have failed to achieve an adequate response to at least one immunosuppressive agent in patients for whom corticosteroids are not clinically appropriate; **OR**
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy, **AND**
- The treatment must not exceed 25 weeks under this restriction.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Vision threatening disease is defined as at least 1 of the following:

(a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent;

(b) A 2-step increase in anterior chamber cells or vitreous haze;

(c) New retinal vasculitis;

(d) New retinal or choroidal lesions;

(e) Other signs of disease progression including visual field changes or electroretinogram changes

A failure to achieve an adequate response is defined as failure to meet one or more of the below criteria:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

Details of prior immunomodulatory agent and corticosteroid treatment, or details of contraindications or developed intolerances necessitating treatment withdrawal, must be documented in the patient's medical record.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include details of vision threatening disease.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***15489***

Vision threatening non-infectious uveitis

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have a documented history of non-infectious uveitis that is vision threatening, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must have demonstrated or sustained an adequate response to treatment prior to having a break in therapy with this drug for this condition, **AND**
- The treatment must not exceed 25 weeks under this restriction.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 14272E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 6 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 14284T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 6 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***17065***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The assessment of response to treatment must be documented in the patient's medical records.

**Authority Required (STREAMLINED)**

***16999***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The assessment of response to treatment must be documented in the patient's medical records.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

15007W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

14958G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17002***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**Authority Required**

***17003***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 14973C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 15019L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***17065***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The assessment of response to treatment must be documented in the patient's medical records.

**Authority Required (STREAMLINED)**

***16999***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The assessment of response to treatment must be documented in the patient's medical records.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

15038L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

15006T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17002***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**Authority Required**

***17003***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

15009Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

15008X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***11867***

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***11906***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority Required**

***11865***

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**

- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12398M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9034L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***14713***

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14730***

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***14656***

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12361N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9078T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***11867***

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***11906***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority Required**

***11865***

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12375H | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9102C | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***14713***

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14730***

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***14656***

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12363Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9104E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

**Initial 2** - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

**(i) Discharge**

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

**(ii) Pain**

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

**(iii) Degree of induration**

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***19157***

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition must be provided by the prescriber at the time of application and documented in the patient's medical records.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

**Authority Required**

***19158***

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under the Continuing treatment restriction, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12405X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8964T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

**Initial 2** - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements.

Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

**(i) Discharge**

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

**(ii) Pain**

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

**(iii) Degree of induration**

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***19157***

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition must be provided by the prescriber at the time of application and documented in the patient's medical records.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

**Authority Required**

***19158***

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under the Continuing treatment restriction, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12446C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

8966X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16993***

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction for patients who:

(i) received fewer than 5 repeats at the time of application; and/or

(ii) required changes to their dosing regimen during this treatment phase.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Authority Required**

***17030***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**

- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12337H | 1 | 5 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15564E | 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12357J | 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15474***

Vision threatening non-infectious uveitis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist, **AND**
- Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent; **OR**
- Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy; **OR**
- Patient must have failed to achieve an adequate response to at least one immunosuppressive agent in patients for whom corticosteroids are not clinically appropriate; **OR**
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy, **AND**
- The treatment must not exceed 25 weeks under this restriction.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Vision threatening disease is defined as at least 1 of the following:

(a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent;

(b) A 2-step increase in anterior chamber cells or vitreous haze;

(c) New retinal vasculitis;

(d) New retinal or choroidal lesions;

(e) Other signs of disease progression including visual field changes or electroretinogram changes

A failure to achieve an adequate response is defined as failure to meet one or more of the below criteria:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

Details of prior immunomodulatory agent and corticosteroid treatment, or details of contraindications or developed intolerances necessitating treatment withdrawal, must be documented in the patient's medical record.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include details of vision threatening disease.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***15489***

Vision threatening non-infectious uveitis

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have a documented history of non-infectious uveitis that is vision threatening, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment prior to having a break in therapy with this drug for this condition, **AND**
- The treatment must not exceed 25 weeks under this restriction.

**Treatment criteria:**

- Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

An adequate response to treatment is defined as:

(a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or

(b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or

(c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or

(d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

| 14244Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 6 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe**

| 15565F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 6 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

| 14748F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 6 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and
- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17002***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**Authority Required**

***17003***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

| 14997H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe**

| 15550K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

| 14998J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 20 mg/0.2 mL syringes; and

- adalimumab 20 mg/0.4 mL syringes.

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17065***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The assessment of response to treatment must be documented in the patient's medical records.

**Authority Required (STREAMLINED)**

***16999***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Population criteria:**

- Patient must have been under 18 years of age at the time of initial treatment with this drug.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The assessment of response to treatment must be documented in the patient's medical records.

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

15039M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 606.96 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**Adalimumab 20 mg/0.2 mL injection, 0.2 mL syringe**

15558W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [AN] |

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

15005R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *606.96 | 25.00 | [a] Amgevita [XT] |

## ADALIMUMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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**Authority Required**

***18813***

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must not have achieved an adequate response to a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of not achieving an adequate response to prior systemic therapy; **OR**

- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below; **OR**
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(c) if applicable, details of intestinal inflammation marker/s; and

(d) if applicable, the CDAI score and the date of assessment; and

(e) the date of the most recent clinical assessment.

Evidence of not achieving an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18814***

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***18815***

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 while off treatment with targeted therapy; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; and evidence of flared disease while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and evidence of flared disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

| 12372E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | *2,042.73 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

| 12419P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | *2,042.73 | 25.00 | [a] Amgevita [AN] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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**Authority Required**

***18593***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be

methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18550***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18549***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; **OR**
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18557***

Severe active juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12364R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

5281Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

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**Authority Required**

***18593***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be

methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18550***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18549***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; **OR**
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18557***

Severe active juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

| 12428D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| 5282B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

**Initial 2** - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

**(i) Discharge**

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

**(ii) Pain**

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

**(iii) Degree of induration**

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***19106***

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition must be provided by the prescriber at the time of application and documented in the patient's medical records.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

**Authority Required**

***19115***

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition; and

(b) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The application must also provide details of the baseline scores of the prior eligibility requirements, including the number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

| 12360M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | *2,042.73 | 25.00 | [a] Amgevita [AN] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

| 12393G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | *2,042.73 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ADALIMUMAB

**Note** The assessment for Juvenile Spondyloarthritis Disease Activity Index score is available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4245319/table/T2/.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17715***

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a diagnosis of enthesitis/spondylitis related juvenile idiopathic arthritis defined by at least one of the following: (i) peripheral arthritis and enthesitis, (ii) inflammatory sacroiliitis on Magnetic Resonance Imaging (MRI) plus at least 3 months of inflammatory back pain, (iii) arthritis or enthesitis plus at least 2 of: (a) sacroiliac joint tenderness, (b) inflammatory back pain, (c) presence of HLA-B27 antigen, (d) acute (symptomatic) anterior uveitis, (e) history of spondyloarthritis in a first-degree relative, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have had a break in treatment of at least 2 years from the most recently prescribed PBS-subsidised biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response for axial disease (sacroiliitis and/or spondylitis), following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) whilst completing an appropriate exercise program, for a total period of 3 months; **OR**
- Patient must have failed to achieve an adequate response for peripheral disease (arthritis and/or enthesitis) following treatment with at least 2 NSAIDs, and either: (i) methotrexate at a dose of 15 mg per square metre (maximum 20 mg)

weekly, (ii) sulfasalazine at a dose of 20 mg/kg (maximum 1 g) twice daily, whilst completing an appropriate exercise program, for a total period of 3 months, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Population criteria:**

- Patient must be under 18 years of age.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If treatment with methotrexate, sulfasalazine or NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to methotrexate, sulfasalazine or NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Juvenile Spondyloarthritis Disease Activity Index score greater than 2; or

(b) persistent symptoms of axial spondylitis or sacroiliitis with prior confirmatory Magnetic Resonance Imaging (MRI) assessed by a clinician experienced with juvenile spondyloarthropathy.

The following must be provided at the time of application and documented in the patient's medical records:

(1) details of prior treatment including dose and duration of treatment; and

(i) if applicable, the baseline Juvenile Spondyloarthritis Disease Activity Index score; or

(ii) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) of the MRI demonstrating inflammatory spondylitis or sacroiliitis; or

(iii) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) demonstrating the presence of HLA-B27.

The Juvenile Spondyloarthritis Disease Activity Index score must be assessed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority Required**

***17731***

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Initial treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

15146E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |
| | | | | | [a] Yuflyma [EW] | |

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

15200B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## ADALIMUMAB

**Note** The assessment for Juvenile Spondyloarthritis Disease Activity Index score is available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4245319/table/T2/.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17715***

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a diagnosis of enthesitis/spondylitis related juvenile idiopathic arthritis defined by at least one of the following: (i) peripheral arthritis and enthesitis, (ii) inflammatory sacroiliitis on Magnetic Resonance Imaging (MRI) plus at least 3 months of inflammatory back pain, (iii) arthritis or enthesitis plus at least 2 of: (a) sacroiliac joint tenderness, (b) inflammatory back pain, (c) presence of HLA-B27 antigen, (d) acute (symptomatic) anterior uveitis, (e) history of spondyloarthritis in a first-degree relative, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have had a break in treatment of at least 2 years from the most recently prescribed PBS-subsidised biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response for axial disease (sacroiliitis and/or spondylitis), following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) whilst completing an appropriate exercise program, for a total period of 3 months; **OR**
- Patient must have failed to achieve an adequate response for peripheral disease (arthritis and/or enthesitis) following treatment with at least 2 NSAIDs, and either: (i) methotrexate at a dose of 15 mg per square metre (maximum 20 mg) weekly, (ii) sulfasalazine at a dose of 20 mg/kg (maximum 1 g) twice daily, whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Population criteria:**

- Patient must be under 18 years of age.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If treatment with methotrexate, sulfasalazine or NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to methotrexate, sulfasalazine or NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Juvenile Spondyloarthritis Disease Activity Index score greater than 2; or

(b) persistent symptoms of axial spondylitis or sacroiliitis with prior confirmatory Magnetic Resonance Imaging (MRI) assessed by a clinician experienced with juvenile spondyloarthropathy.

The following must be provided at the time of application and documented in the patient's medical records:

(1) details of prior treatment including dose and duration of treatment; and

(i) if applicable, the baseline Juvenile Spondyloarthritis Disease Activity Index score; or

(ii) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) of the MRI demonstrating inflammatory spondylitis or sacroiliitis; or

(iii) if applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) demonstrating the presence of HLA-B27.

The Juvenile Spondyloarthritis Disease Activity Index score must be assessed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority Required**

***17731***

Enthesitis/spondylitis related juvenile idiopathic arthritis

Treatment Phase: Initial treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

| 15201C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

| 15161Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate

agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17031***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***17032***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; **OR**
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; **OR**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***17077***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

**Population criteria:**

- Patient must be 6 years of age or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe**

12339K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *2,042.73 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

**adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device**

12374G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *2,042.73 | 25.00 | [a] Amgevita [AN] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

## ADALIMUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17679***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; **OR**
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.

The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority Required**

***17587***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority Required**

***17617***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12450G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *2,042.73 | 25.00 | [a] Amgevita [AN] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

### adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12524E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *2,042.73 | 25.00 | [a] Humira [VE] | [a] Yuflyma [EW] |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18542***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18547***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18537***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Continuing treatment, Whole body or Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***18538***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***18669***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12422T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 495.79 | 25.00 | [a] Hadlima [RF] | [a] Humira [VE] |
| | | | | | [a] Hyrimoz [SZ] | [a] Yuflyma [EW] |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9427E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [XT] | [a] Hadlima [RF] |
| | | | | | [a] Hyrimoz [SZ] | |

## ADALIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- adalimumab 40 mg/0.4 mL pen devices; and
- adalimumab 40 mg/0.8 mL pen devices.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18542***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18547***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***18537***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Continuing treatment, Whole body or Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***18538***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18669***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12377K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Amgevita [AN] | [a] Hadlima [RF] |
| | | | | | [a] Humira [VE] | [a] Hyrimoz [SZ] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12377K | | | | | | [a] Yuflyma [EW] | |

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9428F | 1 | 5 | 0.00 | 439.27 | 25.00 | [a] Abrilada [PF] | [a] Amgevita [XT] |
| | | | | | | [a] Hadlima [RF] | [a] Hyrimoz [SZ] |

## CERTOLIZUMAB PEGOL

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***14542***

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10892G | 1 | 2 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11321W | 1 | 2 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

## CERTOLIZUMAB PEGOL

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required**

***9625***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

| 10897M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

| 11318Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

## CERTOLIZUMAB PEGOL

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***9185***

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

| 10896L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

| 11326D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

## CERTOLIZUMAB PEGOL

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

**Treatment cycles:**

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Treatment phases:**

Initial treatment:

Applications for initial treatment should be made where:

- no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase; or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
- a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
- a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Continuing treatment:

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

Changing the prescribed biological medicine:

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

Baseline measurements to determine response:

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Balance of Supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

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**Authority Required**

***10459***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority Required**

***12392***

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

12013G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

12040Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

## CERTOLIZUMAB PEGOL

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

**Treatment cycles:**

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Treatment phases:**

Initial treatment:

Applications for initial treatment should be made where:

- no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase; or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
- a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note

that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or

- a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Continuing treatment:

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

Changing the prescribed biological medicine:

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

Baseline measurements to determine response:

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Balance of Supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority Required**

***10431***

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

| 12005W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

| 12028C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

## CERTOLIZUMAB PEGOL

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***14499***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

| 13701D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

| 13735X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

## CERTOLIZUMAB PEGOL

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to

provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16725***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***14507***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

| 3425G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

| 11325C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

## CERTOLIZUMAB PEGOL

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***14692***

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9431***

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

| 10137M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

| 11320T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

## CERTOLIZUMAB PEGOL

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***9105***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9063***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

| 10238W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

| 11324B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,036.66 | 25.00 | Cimzia [UC] |

## CERTOLIZUMAB PEGOL

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required**

***14659***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14714***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14686***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10904X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *3,044.49 | 25.00 | Cimzia [UC] |

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

11319R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *3,044.49 | 25.00 | Cimzia [UC] |

## CERTOLIZUMAB PEGOL

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or

- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required**

***18695***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18598***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18634***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes**

10905Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *3,044.49 | 25.00 | Cimzia [UC] |

**certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices**

11322X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *3,044.49 | 25.00 | Cimzia [UC] |

## CERTOLIZUMAB PEGOL

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

**Treatment cycles:**

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Treatment phases:**

Initial treatment:

Applications for initial treatment should be made where:

- no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase; or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
- a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
- a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Continuing treatment:

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

Changing the prescribed biological medicine:

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

Baseline measurements to determine response:

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Balance of Supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

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**Authority Required**

***18335***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***15126***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

(a) the BASDAI score; and

(b) the C-reactive protein (CRP) level.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***15103***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

| 12027B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | *3,044.49 | 25.00 | Cimzia [UC] |

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

| 12063X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | *3,044.49 | 25.00 | Cimzia [UC] |

## CERTOLIZUMAB PEGOL

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***9183***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9073***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9074***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

| 10909E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | *3,044.49 | 25.00 | Cimzia [UC] |

### certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

| 11323Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 0 | 0.00 | *3,044.49 | 25.00 | Cimzia [UC] |

## ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment

authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***14581***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of results;

(b) details of prior treatment, including dose and date/duration of treatment.

(c) If applicable, details of any contraindications/intolerances.

(d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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**Authority Required**

***14582***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Authority Required**

***14603***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of result;

(b) the most recent biological agent and the date of the last continuing prescription.

(c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

| 13687J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Erelzi [SZ] |
| | | | | | | [a] Nepexto [GQ] | |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

| 13698Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Erelzi [SZ] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***14670***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and

(iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Authority Required**

***14673***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***14671***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**

- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

### etanercept 50 mg/mL injection, 4 x 1 mL syringes

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13751R | 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Erelzi [SZ] |

### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13774Y | 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Erelzi [SZ] |
| | | | | | | [a] Nepexto [GQ] | |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16747***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16773***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16713***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***14703***

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### etanercept 50 mg/mL injection, 4 x 1 mL syringes

| 9085E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | | [a] Erelzi [SZ] | |

### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

| 9455P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | | [a] Erelzi [SZ] | [a] Nepexto [GQ] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17355***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16764***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16737***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9064***

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9087G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | [a] Erelzi [SZ] | |

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9457R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | [a] Erelzi [SZ] | [a] Nepexto [GQ] |

## ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16788***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg

weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16709***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16710***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***14488***

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

| 9089J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | | [a] Erelzi [SZ] | |

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

| 9459W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | | [a] Erelzi [SZ] | [a] Nepexto [GQ] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16743***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***16785***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***16779***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16761***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16717***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16716***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16763***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9037P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | 0.00 | *823.74 | 25.00 | Enbrel [PF] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16743***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16785***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16779***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***16761***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16717***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16716***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16763***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

| 9091L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | | [a] Erelzi [SZ] | |

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

| 9461Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | | [a] Erelzi [SZ] | [a] Nepexto [GQ] |

## ETANERCEPT

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase.

Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:

(i) the patient's response to treatment can be quantified from week 12; and

(ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***14513***

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) the PASI score that followed each prior therapy trialled;

(iv) the date the PASI scores were determined.

Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

**Authority Required**

***17001***

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Authority Required**

***14576***

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; **OR**
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; **OR**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Authority Required**

***12261***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2, 3 or 4 treatment (Whole body, or, face/hand/foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 16 weeks treatment available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3, (iv) Initial 4.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Authority Required**

***14553***

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the whole body.

**Treatment criteria:**

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) a disease flare where the PASI score has worsened (increased) by at least 50%, (ii) the current PASI score has returned above 15.

**Clinical criteria:**

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Authority Required**

***14554***

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Authority Required**

***17069***

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Authority Required**

***14577***

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot.

**Treatment criteria:**

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) all PASI sub-measures (redness, thickness, scaling) are rated as 'moderate' to 'severe', (ii) at least 2 of the 3 PASI sub-measures are rated as 'severe' to 'very severe', (iii) the skin area affected has increased by at least 50% since the last administered dose, (iv) the skin area affected is at least 30% of the total skin area of the face/hand/foot.

**Clinical criteria:**

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

1954W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | 0.00 | *823.74 | 25.00 | Enbrel [PF] |

## ETANERCEPT

**Caution** Etanercept 50 mg/mL 1ml pen devices and prefilled syringes are intended for use in children and adolescents weighting 62.5kg or more.

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase.

Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:

(i) the patient's response to treatment can be quantified from week 12; and

(ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***14513***

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) the PASI score that followed each prior therapy trialled;

(iv) the date the PASI scores were determined.

Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

**Authority Required**

***17001***

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Authority Required**

***14576***

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; **OR**
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; **OR**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Authority Required**

***12261***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2, 3 or 4 treatment (Whole body, or, face/hand/foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 16 weeks treatment available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3, (iv) Initial 4.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Authority Required**

***14553***

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the whole body.

**Treatment criteria:**

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) a disease flare where the PASI score has worsened (increased) by at least 50%, (ii) the current PASI score has returned above 15.

**Clinical criteria:**

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Authority Required**

***14554***

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Authority Required**

***17069***

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Authority Required**

***14577***

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot.

**Treatment criteria:**

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) all PASI sub-measures (redness, thickness, scaling) are rated as 'moderate' to 'severe', (ii) at least 2 of the 3 PASI sub-measures are rated as 'severe' to 'very severe', (iii) the skin area affected has increased by at least 50% since the last administered dose, (iv) the skin area affected is at least 30% of the total skin area of the face/hand/foot.

**Clinical criteria:**

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

### etanercept 50 mg/mL injection, 4 x 1 mL syringes

1963H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Enbrel [PF] | [a] Erelzi [SZ] |

### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

1964J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Enbrel [PF] | [a] Erelzi [SZ] |
| | | | | | [a] Nepexto [GQ] | |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

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**Authority Required**

***16775***

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***12123***

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***16718***

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

3448L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *823.74 | 25.00 | Enbrel [PF] |

## ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where

prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***14499***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**

- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

11197H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *823.74 | 25.00 | Enbrel [PF] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***16778***

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

| 11202N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Erelzi [SZ] |
| | | | | | | [a] Nepexto [GQ] | |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

| 11216H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Erelzi [SZ] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***16787***

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

14852Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Erelzi [SZ] | [a] Nepexto [GQ] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

15050D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Erelzi [SZ] |

## ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16725***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14507***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8638P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *823.74 | 25.00 | Enbrel [PF] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the

age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority Required**

***16775***

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***12123***

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***16718***

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### etanercept 50 mg/mL injection, 4 x 1 mL syringes

3449M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Enbrel [PF] | [a] Erelzi [SZ] |

### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

3450N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Enbrel [PF] | [a] Erelzi [SZ] |
| | | | | | [a] Nepexto [GQ] | |

## ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***14499***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

### etanercept 50 mg/mL injection, 4 x 1 mL syringes

11211C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | [a] Erelzi [SZ] | |

### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

11218K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | [a] Erelzi [SZ] | [a] Nepexto [GQ] |

## ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or

- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***14629***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

### etanercept 50 mg/mL injection, 4 x 1 mL syringes

13707K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Erelzi [SZ] |

### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

13708L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Erelzi [SZ] |
| | | | | | [a] Nepexto [GQ] | |

## ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16725***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14507***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9090K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | [a] Erelzi [SZ] | |

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9460X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | [a] Erelzi [SZ] | [a] Nepexto [GQ] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16765***

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***14715***

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***16789***

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8779C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *823.74 | 25.00 | Enbrel [PF] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17326***

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9081***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***16754***

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9036N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *823.74 | 25.00 | Enbrel [PF] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***14683***

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required (STREAMLINED)**

***14701***

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

11215G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Erelzi [SZ] |
| | | | | | [a] Nepexto [GQ] | |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

11217J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Erelzi [SZ] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***16720***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required (STREAMLINED)**

***16795***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11221N | 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ]<br>[a] Nepexto [GQ] | [a] Erelzi [SZ] |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11225T | 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Erelzi [SZ] |

## ETANERCEPT

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient

has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase.

Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:

(i) the patient's response to treatment can be quantified from week 12; and

(ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***14509***

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The assessment of response to treatment must be documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**Authority Required (STREAMLINED)**

***14508***

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The assessment of response to treatment must be documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

| 13693Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 1 | 0.00 | *823.74 | 25.00 | Enbrel [PF] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16765***

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14715***

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***16789***

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9086F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |

| 9086F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Erelzi [SZ] | |

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

| 9456Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | | [a] Erelzi [SZ] | [a] Nepexto [GQ] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17326***

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9081***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***16754***

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

| 9088H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | | [a] Erelzi [SZ] | |

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

| 9458T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | | [a] Erelzi [SZ] | [a] Nepexto [GQ] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

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**Authority Required**

***16727***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs)

which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose; (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial; (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16777***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16728***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; **OR**
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9386***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

3445H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | 0.00 | *823.74 | 25.00 | Enbrel [PF] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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**Authority Required**

***16727***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose; (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial; (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16777***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***16728***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; **OR**
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***9386***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

| 3446J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Enbrel [PF] | [a] Erelzi [SZ] |

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

| 3447K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 823.71 | 25.00 | [a] Enbrel [PF] | [a] Erelzi [SZ] |
| | | | | | | [a] Nepexto [GQ] | |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16792***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17374***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16750***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***16766***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16772***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9429G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *823.74 | 25.00 | Enbrel [PF] |

## ETANERCEPT

**Caution** Etanercept 50 mg/mL 1ml pen devices and prefilled syringes are intended for use in children and adolescents weighting 62.5kg or more.

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase.

Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:

(i) the patient's response to treatment can be quantified from week 12; and

(ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***14509***

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The assessment of response to treatment must be documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**Authority Required (STREAMLINED)**

***14508***

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The assessment of response to treatment must be documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

| 13697X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 823.71 | 25.00 | [a] Enbrel [PF] | [a] Erelzi [SZ] |
| | | | | | | [a] Nepexto [GQ] | |

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

| 13733T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 823.71 | 25.00 | [a] Enbrel [PF] | [a] Erelzi [SZ] |

## ETANERCEPT

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16788***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16709***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**

- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16710***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14488***

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**

- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8637N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | 0.00 | *823.74 | 25.00 | Enbrel [PF] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16747***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***16773***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***16713***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14703***

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

8778B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | 0.00 | *823.74 | 25.00 | Enbrel [PF] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17355***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16764***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16737***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9064***

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

9035M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | 0.00 | *823.74 | 25.00 | Enbrel [PF] |

## ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide

new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16792***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17374***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16750***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***16766***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16772***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.
The authority application must be made in writing and must include:
(a) details of the proposed prescription(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.
An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.
Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
The most recent PASI assessment must be no more than 4 weeks old at the time of application.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.
A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### etanercept 50 mg/mL injection, 4 x 1 mL syringes

9431J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | [a] Erelzi [SZ] | |

### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9462B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 823.71 | 25.00 | [a] Brenzys [OQ] | [a] Enbrel [PF] |
| | | | | | [a] Erelzi [SZ] | [a] Nepexto [GQ] |

## GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.
Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.
Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.
From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.
A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***9745***

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10), **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### golimumab 100 mg/mL injection, 1 mL pen device

11502J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

## GOLIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***14604***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

### golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

13699B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

### golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

13706J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

## GOLIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18560***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***14507***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

| 3428K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

### golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

| 11375Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

## GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***9105***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9063***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

| 3432P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

### golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

| 11373N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

## GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***14692***

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9431***

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

| 3436W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

| 11376R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

## GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***9770***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority Required**

***9651***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### golimumab 100 mg/mL injection, 1 mL pen device

11381B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

## GOLIMUMAB

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

**Treatment cycles:**

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Treatment phases:**

Initial treatment:

Applications for initial treatment should be made where:

- no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase; or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
- a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
- a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Continuing treatment:

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

Changing the prescribed biological medicine:

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

Baseline measurements to determine response:

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Balance of Supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***15125***

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Authority Required**

***10434***

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

11516D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

11521J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

## GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***9822***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment

withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**

- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be aged 18 years or older.

Application for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9823***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9705***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be aged 18 years or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### golimumab 100 mg/mL injection, 1 mL pen device

11382C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 3 | 0 | 0.00 | *3,050.58 | 25.00 | Simponi [JC] |

## GOLIMUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD

treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18633***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs)

which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18635***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18596***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18584***

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3426H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

### golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11372M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

## GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***9155***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16370***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9069***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9064***

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

| 3430M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

### golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

| 11365E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

## GOLIMUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***14670***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***14655***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***14662***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9429***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

| 3434R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL pen device**

| 11361Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

## GOLIMUMAB

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

**Treatment cycles:**

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Treatment phases:**

Initial treatment:

Applications for initial treatment should be made where:

- no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase; or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
- a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
- a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Continuing treatment:

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

Changing the prescribed biological medicine:

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

Baseline measurements to determine response:

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Balance of Supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18429***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***15135***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Clinical criteria:**

- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

(a) the BASDAI score; and

(b) the C-reactive protein (CRP) level.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***15071***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks duration under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***10436***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11538G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

**golimumab 50 mg/0.5 mL injection, 0.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11560K | 1 | 3 | 0.00 | 1,038.79 | 25.00 | Simponi [JC] |

## INFLIXIMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply

treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***17549***

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply for Initial treatment - subcutaneous form

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment with subcutaneous form restriction to complete 22 weeks initial treatment (intravenous and subcutaneous inclusive), **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the Initial treatment - subcutaneous form.

**Population criteria:**

- Patient must be at least 18 years of age.

### infliximab 120 mg/mL injection, 1 mL syringe

12555T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 373.83 | 25.00 | Remsima SC [EW] |

### infliximab 120 mg/mL injection, 1 mL pen device

12566J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 244.26 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from

the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required**

***17552***

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Initial treatment - subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive), **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form.

**Population criteria:**

- Patient must be at least 18 years of age.

### infliximab 120 mg/mL injection, 1 mL syringe

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12550M | 2 | 0 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

### infliximab 120 mg/mL injection, 1 mL pen device

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12584H | 2 | 0 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required**

***18777***

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive), **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

### infliximab 120 mg/mL injection, 1 mL pen device

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12567K | 2 | 0 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

### infliximab 120 mg/mL injection, 1 mL syringe

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12597B | 2 | 0 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required**

***13040***

Severe psoriatic arthritis

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; **OR**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

**Population criteria:**

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

**infliximab 120 mg/mL injection, 1 mL pen device**

| 13056E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 0 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

| 13078H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 0 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required**

***13058***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; **OR**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

**Population criteria:**

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

**infliximab 120 mg/mL injection, 1 mL syringe**

| 13058G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 0 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL pen device**

| 13070X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 0 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required**

***13096***

Ankylosing spondylitis

Treatment Phase: Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis, **AND**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; **OR**
- Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.

**Population criteria:**

- Patient must be at least 18 years of age.

Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.

**infliximab 120 mg/mL injection, 1 mL syringe**

| 13065P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 0 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL pen device**

| 13075E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 0 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17434***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; **OR**
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 120 mg/mL injection, 1 mL syringe**

12552P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL pen device**

12587L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17551***

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug; **OR**
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

### infliximab 120 mg/mL injection, 1 mL syringe

12553Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL pen device**

12554R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***18869***

Severe Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the

need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; **OR**

- Patient must have both: (i) a total PCDAI score of 30 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; **OR**
- Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

**infliximab 120 mg/mL injection, 1 mL pen device**

12560C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

12586K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***17531***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 120 mg/mL injection, 1 mL syringe**

13047Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL pen device**

13054C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same

treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17502***

Ankylosing spondylitis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### infliximab 120 mg/mL injection, 1 mL pen device

13048R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

### infliximab 120 mg/mL injection, 1 mL syringe

13069W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological

medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17431***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment (whole body, or, face/hand/foot) with subcutaneous form or switching from intravenous form to subcutaneous form

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must have both: (i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where the condition is affecting the whole body, an adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by at least 75%, or, is sustained at this level, when compared with the baseline value for this treatment cycle.

Where the condition is affecting the face/hand/foot, an adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) A reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or, sustained at this level, as compared to the baseline values. Indicate the rating (0=none, 1=slight) for each of these 3 observations in the authority application for each affected area; or

(ii) A reduction by at least 75% in the skin area affected, or, sustained at this level, as compared to the baseline value for this treatment cycle.

All assessment findings must be no more than 1 month old at the time of application. Response assessments must be performed on the same affected area assessed at baseline.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### infliximab 120 mg/mL injection, 1 mL syringe

13050W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL pen device**

13076F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

**Initial 2** - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Authority Required**

***19178***

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive), **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**infliximab 120 mg/mL injection, 1 mL pen device**

| 13061K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 0 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

| 13074D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 0 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of supply listing - apply under this listing if the treatment phase is yet to be completed; the following prescription is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a patient is demonstrating a response to treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***18987***

Severe Crohn disease

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have received treatment with the PBS-subsidised IV formulation of this drug for this condition; **OR**
- Patient must have received an approved PBS authority prescription for treatment with the IV formulation of this drug for this condition; **OR**
- Patient must not have received treatment with the IV formulation of this drug, but has met the restrictions criteria as specified in the Initial 1, 2, or 3 for the IV formulation for this condition.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

The following information must be provided for patients who have not received the IV formulation as loading dose(s), but has met the restrictions criteria as specified in the Initial 1, 2, or 3 for the IV formulation:

(i) reason for loading doses being omitted; and

(ii) if applicable, details of prior systemic therapy [dosage, date of commencement and duration of therapy]; and

(iii) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(iv) if applicable, details of intestinal inflammation marker/s; and

(v) if applicable, the PCDAI or CDAI score and the date of assessment; and

(vi) the date of the most recent clinical assessment.

**infliximab 120 mg/mL injection, 1 mL pen device**

12551N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

12585J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

**Initial 2** - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

**(i) Discharge**

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

**(ii) Pain**

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

**(iii) Degree of induration**

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***19110***

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

**infliximab 120 mg/mL injection, 1 mL pen device**

13060J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13073C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 5 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

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**Authority Required**

***13045***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

**Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

**infliximab 120 mg/mL injection, 1 mL syringe**

12561D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL pen device**

12575W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18659***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

**Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

**infliximab 120 mg/mL injection, 1 mL syringe**

12576X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL pen device**

12577Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Authority Required**

***13077***

Ankylosing spondylitis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

**Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

### infliximab 120 mg/mL injection, 1 mL pen device

| 13049T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

### infliximab 120 mg/mL injection, 1 mL syringe

| 13057F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

**Initial 2** - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

**(i) Discharge**

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

**(ii) Pain**

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

**(iii) Degree of induration**

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of supply listing - apply under this listing if the treatment phase is yet to be completed; the following prescription is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a patient is demonstrating a response to treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***19209***

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have received treatment with the PBS-subsidised IV formulation of this drug for this condition; **OR**
- Patient must have received an approved PBS authority prescription for treatment with the IV formulation of this drug for this condition; **OR**
- Patient must not have received treatment with the IV formulation of this drug, but has met the restrictions criteria as specified in the Initial 1 or 2 for the IV formulation for this condition.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The following information must be provided for patients who have not received the IV formulation as loading dose(s), but has met the restrictions criteria as specified in the Initial 1 or 2 for the IV formulation:

(i) reason for loading doses being omitted; and

(ii) if applicable, baseline number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition; and

(iii) if applicable, current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition; and

(iv) if applicable, details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

**infliximab 120 mg/mL injection, 1 mL pen device**

13055D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13072B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***18662***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

**Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

**infliximab 120 mg/mL injection, 1 mL pen device**

13062L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

**infliximab 120 mg/mL injection, 1 mL syringe**

13067R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 2 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

## INFLIXIMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of Supply listing - apply under this listing if the treatment phase (Initial treatment, First Continuing treatment, Subsequent Continuing treatment) is yet to be completed; the following authority application is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a treatment phase is concluding/has concluded; this typically occurs for the dose due at treatment week 16, 40, 64, 88 etc.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

**Authority Required**

***13097***

Severe psoriatic arthritis

Treatment Phase: Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made

**Treatment criteria:**

- Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine, **AND**
- Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The PBS administrator will confirm that:

(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;

(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.

### infliximab 120 mg/mL injection, 1 mL syringe

| 13066Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *738.30 | 25.00 | Remsima SC [EW] |

### infliximab 120 mg/mL injection, 1 mL pen device

| 13077G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *479.16 | 25.00 | Remsima SC [EW] |

## *Interleukin inhibitors*

## BIMEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18083***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18084***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18064***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18109***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18065***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18067***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**

- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14449***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13644D | 1 | 4 | 0.00 | 3,457.56 | 25.00 | Bimzelx [UC] |

**bimekizumab 320 mg/2 mL injection, 2 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15256Y | 1 | 4 | 0.00 | 3,457.56 | 25.00 | Bimzelx [UC] |

## BIMEKIZUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17643***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years), or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a dermatologist.

### bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

15110G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | 0.00 | *6,805.76 | 25.00 | Bimzelx [UC] |

### bimekizumab 320 mg/2 mL injection, 2 mL pen devices

15119R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 2 | 3 | 0.00 | *6,805.76 | 25.00 | Bimzelx [UC] |

## BIMEKIZUMAB

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

**Treatment cycles:**

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Treatment phases:**

Initial treatment:

Applications for initial treatment should be made where:

- no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase; or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
- a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
- a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Continuing treatment:

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

Changing the prescribed biological medicine:

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

Baseline measurements to determine response:

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Balance of Supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***15140***

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***10434***

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

14589W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 3,457.56 | 25.00 | Bimzelx [UC] |

## BIMEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***15902***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***15903***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

| 14590X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 3,457.56 | 25.00 | Bimzelx [UC] |

## BIMEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing

treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***15937***

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***15949***

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

14602M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 3,457.56 | 25.00 | Bimzelx [UC] |

## BIMEKIZUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***17646***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority Required**

***17591***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2025, **AND**
- Patient must have had a Hurley stage II or III with an abscess and inflammatory nodule (AN) count greater than or equal to 3 prior to starting treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment by achieving Hidradenitis Suppurativa Clinical Response (HiSCR) after 12 weeks of treatment if the patient has been treated with this drug for this condition for 12 weeks or longer, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Assessment of disease severity must not have been more than 4 weeks old at the time treatment with this drug was initiated.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal. The name of the one course of antibiotics must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal.

(v) the Hidradenitis Suppurativa Clinical Response (HiSCR) result if the patient has received 12 weeks or more of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices**

15133L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 3,457.56 | 25.00 | Bimzelx [UC] |

**bimekizumab 320 mg/2 mL injection, 2 mL pen devices**

15112J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 3,457.56 | 25.00 | Bimzelx [UC] |

## BIMEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of

disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18116***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18066***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***10807***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

13652M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 3,457.56 | 25.00 | Bimzelx [UC] |

### bimekizumab 320 mg/2 mL injection, 2 mL pen devices

15262G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 3,457.56 | 25.00 | Bimzelx [UC] |

## BIMEKIZUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***17585***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; **OR**

- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.

The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority Required**

***17595***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***17596***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

### bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

| 15116N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *6,805.76 | 25.00 | Bimzelx [UC] |

### bimekizumab 320 mg/2 mL injection, 2 mL pen devices

| 15131J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *6,805.76 | 25.00 | Bimzelx [UC] |

## BIMEKIZUMAB

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

**Treatment cycles:**

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Treatment phases:**

Initial treatment:

Applications for initial treatment should be made where:

- no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase; or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
- a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
- a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Continuing treatment:

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

Changing the prescribed biological medicine:

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

Baseline measurements to determine response:

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Balance of Supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15891***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***15149***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

(a) the BASDAI score; and

(b) the C-reactive protein (CRP) level.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***15150***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***14217***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14593C | 1 | 1 | 0.00 | 3,457.56 | 25.00 | Bimzelx [UC] |

## BIMEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***15857***

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***15938***

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***15874***

Ankylosing spondylitis

Treatment Phase: Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***15939***

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

14618J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 3,457.56 | 25.00 | Bimzelx [UC] |

## BIMEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***15940***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**

- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16396***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***15916***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9064***

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices

14625R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 3,457.56 | 25.00 | Bimzelx [UC] |

## GUSELKUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***11919***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***11890***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.

Where an assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***11979***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9172***

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority Required**

***11917***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.

Where an assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***11918***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**guselkumab 100 mg/mL injection, 1 x 1 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12568L | 1 | 2 | 0.00 | 3,654.31 | 25.00 | Tremfya [JC] |

**guselkumab 100 mg/mL injection, 1 x 1 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12590P | 1 | 2 | 0.00 | 3,654.31 | 25.00 | Tremfya [JC] |

## GUSELKUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18608***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18692***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18672***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18643***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***18713***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***18698***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18714***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***18571***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18583***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18530***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Continuing treatment, Whole body or Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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### guselkumab 100 mg/mL injection, 1 x 1 mL syringe

11614G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 3,654.31 | 25.00 | Tremfya [JC] |

## IXEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent

continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***11981***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***11958***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***11834***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count, ESR and/or CRP must be no more than 4 weeks old at the time of application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9172***

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority Required**

***11959***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***11918***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11623R | 1 | 2 | 0.00 | 3,291.30 | 25.00 | Taltz [LY] |

## IXEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18653***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of

at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16785***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16779***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18647***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18529***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

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Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18582***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***18644***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

11032P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 3,291.30 | 25.00 | Taltz [LY] |

## IXEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***14692***

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9431***

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

12209N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 3,291.30 | 25.00 | Taltz [LY] |

## IXEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18645***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18701***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18530***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Continuing treatment, Whole body or Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

11033Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 3,291.30 | 25.00 | Taltz [LY] |

## IXEKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing

spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***14670***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14655***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14662***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9429***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

12217B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 3,291.30 | 25.00 | Taltz [LY] |

## RISANKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater

than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18575***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18576***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18715***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18677***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18664***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18610***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18646***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 28 weeks treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**risankizumab 150 mg/mL injection, 1 mL pen device**

| 14111Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 5,209.24 | 25.00 | Skyrizi [VE] |

## RISANKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***15902***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***15903***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### risankizumab 150 mg/mL injection, 1 mL pen device

14713J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 5,209.24 | 25.00 | Skyrizi [VE] |

## RISANKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18571***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18583***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18530***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Continuing treatment, Whole body or Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**risankizumab 150 mg/mL injection, 1 mL pen device**

| 14142H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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## RISANKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***16338***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16391***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16339***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***16340***

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### risankizumab 150 mg/mL injection, 1 mL pen device

14732J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 5,209.24 | 25.00 | Skyrizi [VE] |

## SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**

***18653***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***16785***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***16779***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18647***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18529***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18582***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

10910F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 0 | 0.00 | *5,304.36 | 25.00 | Cosentyx [NV] |

**Secukinumab 300 mg/2 mL injection, 2 mL pen device**

15028Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 0 | 0.00 | *5,304.32 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same

treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***9429***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### secukinumab 150 mg/mL injection, 1 mL pen device

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10893H | 1 | 2 | 0.00 | 694.23 | 25.00 | Cosentyx [NV] |

### Secukinumab 300 mg/2 mL injection, 2 mL pen device

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14956E | 1 | 2 | 0.00 | 1,373.04 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15807***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment.

**Treatment criteria:**

- Must be treated by a dermatologist.

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

| 14164L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 1,373.05 | 25.00 | Cosentyx [NV] |

**Secukinumab 300 mg/2 mL injection, 2 mL pen device**

| 14983N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 1,373.04 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***14692***

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9431***

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**secukinumab 150 mg/mL injection, 1 mL pen device**

10906B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 694.23 | 25.00 | Cosentyx [NV] |

**Secukinumab 300 mg/2 mL injection, 2 mL pen device**

15029B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,373.04 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***8831***

Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

| 10494H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 1,373.05 | 25.00 | Cosentyx [NV] |

**Secukinumab 300 mg/2 mL injection, 2 mL pen device**

| 14971Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 1,373.04 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***9064***

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**secukinumab 150 mg/mL injection, 1 mL pen device**

| 10898N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 694.23 | 25.00 | Cosentyx [NV] |

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

| 10901R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 1,373.05 | 25.00 | Cosentyx [NV] |

**Secukinumab 300 mg/2 mL injection, 2 mL pen device**

| 15027X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 1,373.04 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

**Treatment cycles:**

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Treatment phases:**

Initial treatment:

Applications for initial treatment should be made where:

- no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase; or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
- a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
- a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Continuing treatment:

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

Changing the prescribed biological medicine:

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

Baseline measurements to determine response:

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Balance of Supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***10431***

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### secukinumab 150 mg/mL injection, 1 mL pen device

12307R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 694.23 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic

use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17671***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

| 14146M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,373.05 | 25.00 | Cosentyx [NV] |

### Secukinumab 300 mg/2 mL injection, 2 mL pen device

| 14970X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,373.04 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

**Treatment cycles:**

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Treatment phases:**

Initial treatment:

Applications for initial treatment should be made where:

- no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase; or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
- a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
- a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Continuing treatment:

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

Changing the prescribed biological medicine:

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

Baseline measurements to determine response:

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Balance of Supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***11390***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patients) restriction to complete 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***12392***

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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### secukinumab 150 mg/mL injection, 1 mL pen device

12297F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 694.23 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing

spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***14670***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14655***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14662***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### secukinumab 150 mg/mL injection, 1 mL pen device

10890E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 0 | 0.00 | *2,718.40 | 25.00 | Cosentyx [NV] |

### Secukinumab 300 mg/2 mL injection, 2 mL pen device

14957F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 4 | 0 | 0.00 | *5,304.32 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***9105***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9063***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**secukinumab 150 mg/mL injection, 1 mL pen device**

| 10895K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 694.23 | 25.00 | Cosentyx [NV] |

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

| 10899P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,373.05 | 25.00 | Cosentyx [NV] |

**Secukinumab 300 mg/2 mL injection, 2 mL pen device**

| 15018K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,373.04 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

**Treatment cycles:**

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Treatment phases:**

Initial treatment:

Applications for initial treatment should be made where:

- no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase; or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
- a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
- a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Continuing treatment:

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

Changing the prescribed biological medicine:

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

Baseline measurements to determine response:

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Balance of Supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18499***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***15137***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

(a) the BASDAI score; and

(b) the C-reactive protein (CRP) level.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***15158***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**secukinumab 150 mg/mL injection, 1 mL pen device**

12321L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 5 | 0 | 0.00 | *3,370.64 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18571***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18583***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18530***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Continuing treatment, Whole body or Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

| 10425Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,373.05 | 25.00 | Cosentyx [NV] |

**Secukinumab 300 mg/2 mL injection, 2 mL pen device**

| 14972B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,373.04 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte

sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***9155***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16382***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***9069***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**secukinumab 150 mg/mL injection, 1 mL pen device**

| 10900Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 0 | 0.00 | *2,718.40 | 25.00 | Cosentyx [NV] |

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

| 10894J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 0 | 0.00 | *5,304.36 | 25.00 | Cosentyx [NV] |

**Secukinumab 300 mg/2 mL injection, 2 mL pen device**

| 14955D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 0 | 0.00 | *5,304.32 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological

medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***17644***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; **OR**
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.

The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

This restriction is intended for induction dosing only.

The details of two proposed prescriptions should be submitted with every initial application for this drug.

Prescribing the 150 mg presentation:

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

Prescribing the 300 mg presentation:

One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority Required**

***17681***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The details of two proposed prescriptions should be submitted with every initial application for this drug.

Prescribing the 150 mg presentation:

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

Prescribing the 300 mg presentation:

One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats.

This restriction is intended for induction dosing only.

**Authority Required**

***17680***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The details of two proposed prescriptions should be submitted with every initial application for this drug.

Prescribing the 150 mg presentation:

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

Prescribing the 300 mg presentation:

One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats.

This restriction is intended for induction dosing only.

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

| 14154Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 0 | 0.00 | *5,304.36 | 25.00 | Cosentyx [NV] |

**Secukinumab 300 mg/2 mL injection, 2 mL pen device**

| 15004Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 0 | 0.00 | *5,304.32 | 25.00 | Cosentyx [NV] |

## SECUKINUMAB

**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab or secukinumab prior to 1 December 2025 is considered to start their first cycle as of 1 December 2025.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment with another biological medicine may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing/swapping therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***17670***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; **OR**
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.

The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The details of two proposed prescriptions should be submitted with every initial application for this drug.

Prescribing the 150 mg presentation:

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

Prescribing the 300 mg presentation:

One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority Required**

***17594***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The details of two proposed prescriptions should be submitted with every initial application for this drug.

Prescribing the 150 mg presentation:

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

Prescribing the 300 mg presentation:

One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats.

**Authority Required**

***17590***

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(i) the Hurley stage grading; and

(ii) the AN count.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription(s); and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The details of two proposed prescriptions should be submitted with every initial application for this drug.

Prescribing the 150 mg presentation:

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

Prescribing the 300 mg presentation:

One prescription should be for the induction doses, containing a quantity of 4 doses of 300 mg and no repeats and the second prescription should be for 1 dose of 300 mg and 3 repeats.

**secukinumab 150 mg/mL injection, 2 x 1 mL pen devices**

| 14161H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 1,373.05 | 25.00 | Cosentyx [NV] |

**Secukinumab 300 mg/2 mL injection, 2 mL pen device**

| 15030C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 1,373.04 | 25.00 | Cosentyx [NV] |

## TILDRAKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and

scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18614***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18680***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18704***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18717***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18681***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18682***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18705***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tildrakizumab 100 mg/mL injection, 1 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11616J | 1 | 2 | 0.00 | 3,146.00 | 25.00 | Ilumya [RA] |

## TILDRAKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24

weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***19006***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment (whole body) restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the continuing treatment (face/hand/foot) restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### Tildrakizumab 100 mg/mL injection, 2 x 1 mL syringes

15448C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 6,159.64 | 25.00 | Ilumya [RA] |

## TILDRAKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***19029***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have both: (i) experienced an adequate response following the most recent course of treatment at the 100 mg dosage regimen and (ii) the treating physician determined that a more satisfactory response can be achieved at the 200 mg dosage regimen; **OR**
- Patient must have demonstrated an adequate response to the most recent course of treatment with this drug at the 200 mg dosage regimen, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to not have responded to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient does not demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Tildrakizumab 100 mg/mL injection, 2 x 1 mL syringes**

15449D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 6,159.64 | 25.00 | Ilumya [RA] |

## TILDRAKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***19028***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have both: (i) experienced an adequate response following the most recent course of treatment at the 100 mg dosage regimen and (ii) the treating physician determined that a more satisfactory response can be achieved at the 200 mg dosage regimen; **OR**
- Patient must have demonstrated an adequate response to the most recent course of treatment with this drug at the 200 mg dosage regimen, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to not have responded to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient does not demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### Tildrakizumab 100 mg/mL injection, 2 x 1 mL syringes

15458N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 6,159.64 | 25.00 | Ilumya [RA] |

## TILDRAKIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18571***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18583***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18530***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Continuing treatment, Whole body or Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### tildrakizumab 100 mg/mL injection, 1 mL syringe

11613F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 3,146.00 | 25.00 | Ilumya [RA] |

## TOCILIZUMAB

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

**Treatment cycles**

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

1) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy; and
2) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

**Prescribing under the correct 'Treatment Phase' listing for the authority application**

Initial treatment

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

Continuing treatment

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

Baseline measurements to determine response

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***14080***

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient weighing at least 30 kg)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; **OR**
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The assessment of response to prior treatment must be documented in the patient's medical records.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(b) details of prior treatment including dose and duration of treatment; and

(c) the pathology reports detailing CRP and platelet count where appropriate.

**Authority Required**

***14175***

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing at least 30 kg)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***14147***

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months in a patient weighing at least 30 kg)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); **OR**
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Population criteria:**

- Patient must be under 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12083Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12095N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

**Treatment cycles**

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

1) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy; and
2) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

**Prescribing under the correct 'Treatment Phase' listing for the authority application**

Initial treatment

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

Continuing treatment

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

Baseline measurements to determine response

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***14094***

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient weighing less than 30 kg)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; **OR**
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The assessment of response to prior treatment must be documented in the patient's medical records.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and

(b) the details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Authority Required**

***14182***

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing less than 30 kg)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***14121***

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of a new treatment cycle after a break of more than 12 months in a patient weighing less than 30 kg)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); **OR**
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Population criteria:**

- Patient must be under 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12085C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12105D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

**Treatment cycles:**

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment Phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission:

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required (STREAMLINED)**

***17742***

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must be 30kg or over, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

| 11720W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

| 11742B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients over 18 years who have a history of juvenile idiopathic arthritis with onset prior to the age of 18 years.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS-subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18638***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12761P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12762Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18639***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12767Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12768B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***19002***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab.

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**

- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Population criteria:**

- Patient must be under 18 years of age.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

| 15444W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 760.99 | 25.00 | Avtozma [EW] |

### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

| 15456L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 760.99 | 25.00 | Avtozma [EW] |

## TOCILIZUMAB

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

**Treatment cycles:**

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment Phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission:

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***17710***

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must be under 30kg, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

13301C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

13306H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***19020***

Active giant cell arteritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed 52 weeks in total including initial and continuing applications.

**Treatment criteria:**

- Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

15421P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 6 | 0.00 | 760.99 | 25.00 | Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

15457M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 6 | 0.00 | 760.99 | 25.00 | Avtozma [EW] |

## TOCILIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***18939***

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

| 15432F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 760.99 | 25.00 | Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

| 15454J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 760.99 | 25.00 | Avtozma [EW] |

## TOCILIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or

the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

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**Authority Required**

***18944***

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18945***

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient doses for up to 24 weeks treatment. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18947***

Severe active juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11730J | 1 | 5 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11750K | 1 | 5 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

**Treatment cycles**

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

1) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy; and
2) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

**Prescribing under the correct 'Treatment Phase' listing for the authority application**

Initial treatment

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

Continuing treatment

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing

treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

Baseline measurements to determine response

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required**

***10560***

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months) - in a patient of any weight being administered a subcutaneous form of this biological medicine

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12094M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12102Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***9180***

Active giant cell arteritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed 52 weeks in total including initial and continuing applications.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

| 11721X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 6 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

| 11722Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 6 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients back to tocilizumab from another biological medicine, where treatment was changed due to unavailability of tocilizumab due to the critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***18601***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12792G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12806B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***14499***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

13685G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

13720D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients back to tocilizumab from another biological medicine, where treatment was changed due to unavailability of tocilizumab due to the critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***19004***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

| 15446Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 760.99 | 25.00 | Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

| 15492J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 760.99 | 25.00 | Avtozma [EW] |

## TOCILIZUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16725***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***14507***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

10954M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11567T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

**Treatment cycles**

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

1) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy; and
2) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

**Prescribing under the correct 'Treatment Phase' listing for the authority application**

Initial treatment

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

Continuing treatment

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

Baseline measurements to determine response

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***14088***

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment in a patient weighing at least 30 kg

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The following reports must be documented in the patient's medical records where appropriate:

(a) baseline and current pathology reports detailing C-reactive protein (CRP) levels; and

(b) baseline and current pathology reports detailing platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

12084B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

12099T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

**Treatment cycles**

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

1) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy; and
2) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

**Prescribing under the correct 'Treatment Phase' listing for the authority application**

Initial treatment

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

Continuing treatment

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

Baseline measurements to determine response

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***14084***

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment in a patient weighing less than 30 kg

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12086D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12090H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment

authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***19036***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the prescribing.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Authority Required (STREAMLINED)**

***18938***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

| 15441Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 760.99 | 25.00 | Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

| 15462T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 760.99 | 25.00 | Avtozma [EW] |

## TOCILIZUMAB

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***19268***

Active giant cell arteritis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.

**Clinical criteria:**

- Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause, **AND**
- Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; **OR**
- Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; **OR**
- Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging, **AND**
- Patient must have had a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis, **AND**
- Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; **OR**
- Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT at diagnosis; **OR**
- Patient must have had evidence of positive temporal artery halo sign by ultrasound (US) at diagnosis, **AND**
- The treatment must be in combination with a tapering course of corticosteroids, **AND**
- The treatment must not exceed 52 weeks in total including initial and continuing applications.

**Population criteria:**

- Patient must be aged 50 years or older.

Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS and must include:

(a) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR or CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging; and

(b) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has been diagnosed with giant cell arteritis with a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

11743C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11744D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014:**

Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after 24 months break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

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**Authority Required**

***18696***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**

- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose; (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial; (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18661***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18670***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; **OR**
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18565***

Severe active juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

| 11725D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

| 11741Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

**Treatment cycles:**

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment Phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a

treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission:

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***17760***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months.

**Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Authority Required**

***17748***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Authority Required**

***17709***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority Required**

***9477***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 16 or 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 or 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 or 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions for patients 30 kg or over; **OR**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions for patients under 30 kg.

### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

| 11734N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

### tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

| 11748H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

## TOCILIZUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or

- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***18948***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of results;

(b) details of prior treatment, including dose and date/duration of treatment.

(c) If applicable, details of any contraindications/intolerances.

(d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Authority Required**

***19027***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Authority Required**

***19041***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of result;

(b) the most recent biological agent and the date of the last continuing prescription.

(c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

| 15445X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 760.99 | 25.00 | Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

| 15491H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 760.99 | 25.00 | Avtozma [EW] |

## TOCILIZUMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18534***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18562***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18604***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18584***

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

10951J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 760.99 | 25.00 | [a] Actemra Subcutaneous Injection [RO] | [a] Avtozma [EW] |

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

11565Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 760.99 | 25.00 | [a] Actemra ACTPen [RO] | [a] Avtozma [EW] |

## USTEKINUMAB

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

**Initial 2** - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

**(i) Discharge**

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

**(ii) Pain**

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

**(iii) Degree of induration**

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***19171***

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition must be provided by the prescriber at the time of application and documented in the patient's medical records.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

**Authority Required**

***19172***

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition; and

(b) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The application must also provide details of the baseline scores of the prior eligibility requirements, including the number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

**Authority Required**

***19149***

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1 or Initial 2), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

### ustekinumab 90 mg/mL injection, 1 mL syringe

13805N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 986.28 | 25.00 | [a] Stelara [JC] | [a] Steqeyma [EW] |
| | | | | | [a] Wezlana [TN] | |

## USTEKINUMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Authority Required**

***18825***

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must not have achieved an adequate response to a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of not achieving an adequate response to prior systemic therapy; **OR**
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below; **OR**
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(c) if applicable, details of intestinal inflammation marker/s; and

(d) if applicable, the CDAI score and the date of assessment; and

(e) the date of the most recent clinical assessment.

Evidence of not achieving an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18856***

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***18785***

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 while off treatment with targeted therapy; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; and evidence of flared disease while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and evidence of flared disease while off treatment with targeted therapy, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***18885***

Severe Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

**Clinical criteria:**

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

A maximum number of repeats of this drug consisting of up to 1 repeat for patients whose dosing frequency is every 12 weeks and up to 2 repeats for patients whose dosing frequency is every 8 weeks, will be authorised.

Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend treatment beyond 24 weeks.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

**Authority Required**

***18827***

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, Continuing, or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment), **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

### ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe

14898D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2 | 0 | 0.00 | *1,579.14 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

### ustekinumab 90 mg/mL injection, 1 mL syringe

14934B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 986.28 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** **Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** The 28-weeks of treatment provided by this listing is intended to cover doses occurring at week 0, week 4 and week 16. Based on body weight, request an amount of biological medicine sufficient to cover a dose occurring at these timepoints. The original prescription is intended to cover a dose at week 0 and the 2 repeat prescriptions available are intended to cover doses at week 4 and week 16.

The dose due at week 28 is obtained with the first prescription obtained under the 'Continuing treatment' phase. Remind the patient to return for clinical review at approximately week 24 of treatment to enable ample time to obtain the authority application enabling dosing from week 28 and onwards.

Document the patient's baseline disease severity indices scores in their medical record, in addition to providing them in this authority application, to ensure:

(i) the patient's response to treatment can be quantified; and

(ii) in the case of the patient switching therapy for this condition, the baseline scores for the initial application will be available.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***17070***

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per

square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) the PASI score that followed each prior therapy trialled;

(iv) the date the PASI scores were determined.

Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17067***

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.

Response to preceding supply:

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

(i) an absence of an adequate response; or

(ii) an intolerance to that treatment; or

(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17068***

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; **OR**
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; **OR**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***12334***

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2 or 3 treatment (Whole body, or, face/hand/foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 3 doses available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3.

**Clinical criteria:**

- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of 3 doses available under any of the initial treatment phases.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***17071***

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17039***

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change or recommencement of treatment after a break in biological medicine of less than 5 years

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.

Response to preceding supply:

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or is sustained at this level, when compared with the baseline value for this treatment cycle.

Change in therapy:

If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

(i) there is an absence of an adequate response to that treatment; or

(ii) there was an intolerance to that treatment; or

(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above

Recommencing therapy:

If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:

(i) an absence of an adequate response; or

(ii) an intolerance to that treatment; or

(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.

The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

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HOBART TAS 7001

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

| 12669T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 794.25 | 25.00 | [a] Stelara [JC] | [a] Wezlana [TN] |

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe**

| 14879D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 794.25 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

**ustekinumab 90 mg/mL injection, 1 mL syringe**

| 14897C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 986.28 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16894***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16900***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16920***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16922***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16832***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16868***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***11120***

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9304Q | 1 | 2 | 0.00 | 794.25 | 25.00 | [a] Stelara [JC] | [a] Wezlana [TN] |

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe**

| 14892T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 794.25 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

**ustekinumab 90 mg/mL injection, 1 mL syringe**

| 14935C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 986.28 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Authority Required**

***18825***

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must not have achieved an adequate response to a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of not achieving an adequate response to prior systemic therapy; **OR**
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below; **OR**
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(c) if applicable, details of intestinal inflammation marker/s; and

(d) if applicable, the CDAI score and the date of assessment; and

(e) the date of the most recent clinical assessment.

Evidence of not achieving an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18856***

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**

- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***18785***

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 while off treatment with targeted therapy; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; and evidence of flared disease while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and evidence of flared disease while off treatment with targeted therapy, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***18885***

Severe Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

**Clinical criteria:**

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

A maximum number of repeats of this drug consisting of up to 1 repeat for patients whose dosing frequency is every 12 weeks and up to 2 repeats for patients whose dosing frequency is every 8 weeks, will be authorised.

Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested through the

Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend treatment beyond 24 weeks.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

**Authority Required**

***18826***

Severe Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A maximum number of repeats of this drug consisting of up to 1 repeat for patients whose dosing frequency is every 12 weeks and up to 2 repeats for patients whose dosing frequency is every 8 weeks, will be authorised.

Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested by applying through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the continuing treatment period.

**Authority Required**

***18827***

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, Continuing, or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment), **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 11178H | 2 | 0 | 0.00 | *1,579.14 | 25.00 | [a] Stelara [JC] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16818***

Severe chronic plaque psoriasis

Treatment Phase: First continuing, Subsequent continuing treatment - balance of supply (Whole body, or, face/hand/foot)

**Treatment criteria:**

- Must be treated by a dermatologist, **AND**

- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but the full number of repeats available under the continuing treatment phase was not prescribed.

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

12662K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 794.25 | 25.00 | [a] Stelara [JC] | [a] Wezlana [TN] |

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe**

14890Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 794.25 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16854***

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe

14877B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 794.25 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

### ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

15368W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 794.25 | 25.00 | Wezlana [TN] |

## USTEKINUMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***18721***

Severe Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**

- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14909Q | 2 | 2 | 0.00 | *1,579.14 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15397J | 2 | 2 | 0.00 | *1,579.14 | 25.00 | Wezlana [TN] |

**ustekinumab 90 mg/mL injection, 1 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14926N | 1 | 2 | 0.00 | 986.28 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16945***

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### ustekinumab 90 mg/mL injection, 1 mL syringe

14918E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 986.28 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***16886***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Whole body) - treatment covering week 28 and onwards restrictions, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The assessment of response to treatment must be provided in this application and documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**Authority Required (STREAMLINED)**

***16911***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment (Face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards restrictions, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The assessment of response to treatment must be provided in this application and documented in the patient's medical records.

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe**

| 14933Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 794.25 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

| 15390B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 794.25 | 25.00 | Wezlana [TN] |

**ustekinumab 90 mg/mL injection, 1 mL syringe**

| 14878C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 986.28 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16925***

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16856***

Severe psoriatic arthritis

Treatment Phase: First continuing, Subsequent continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14908P | 1 | 1 | 0.00 | 794.25 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16835***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required (STREAMLINED)**

***16967***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe

14944M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 794.25 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

| 15400M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 794.25 | 25.00 | Wezlana [TN] |

**ustekinumab 90 mg/mL injection, 1 mL syringe**

| 14917D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 986.28 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16896***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16927***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***12156***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe**

| 14899E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 794.25 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

**ustekinumab 90 mg/mL injection, 1 mL syringe**

| 14893W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 986.28 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

**Initial 2** - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

**(i) Discharge**

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

**(ii) Pain**

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

**(iii) Degree of induration**

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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**Authority Required**

***19193***

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition must be provided by the prescriber at the time of application and documented in the patient's medical records.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A maximum number of repeats of this drug consisting of up to 1 repeat for patients whose dosing frequency is every 12 weeks and up to 2 repeats for patients whose dosing frequency is every 8 weeks, will be authorised.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

**ustekinumab 90 mg/mL injection, 1 mL syringe**

| 13789R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 986.28 | 25.00 | [a] Stelara [JC] | [a] Steqeyma [EW] |
| | | | | | | [a] Wezlana [TN] | |

## USTEKINUMAB

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

**Initial 2** - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

**(i) Discharge**

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

**(ii) Pain**

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

**(iii) Degree of induration**

- 0 - no induration

- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***19174***

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

### ustekinumab 90 mg/mL injection, 1 mL syringe

14907N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 986.28 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** For the next authority approval following this one, aim to conduct and submit the PASI assessment at approximately 4 weeks prior to when a new authority application is due to ensure uninterrupted supply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18723***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The assessment of response to treatment must be provided in this application and documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**Authority Required**

***18898***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment (Face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The assessment of response to treatment must be provided in this application and documented in the patient's medical records.

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14891R | 1 | 1 | 0.00 | 794.25 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

**ustekinumab 90 mg/mL injection, 1 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14943L | 1 | 1 | 0.00 | 986.28 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16925***

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16856***

Severe psoriatic arthritis

Treatment Phase: First continuing, Subsequent continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***16924***

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

10767Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 794.25 | 25.00 | [a] Stelara [JC] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete.

There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Increase in the maximum number of repeats of up to 2 may be authorised in patients whose dosing frequency is every 8 weeks.

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**Authority Required**

***16915***

Moderate to severe ulcerative colitis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***16973***

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***16916***

Moderate to severe ulcerative colitis

Treatment Phase: First continuing, Subsequent continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

### ustekinumab 90 mg/mL injection, 1 mL syringe

13261Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 986.28 | 25.00 | [a] Stelara [JC]<br>[a] Wezlana [TN] | [a] Steqeyma [EW] |

## USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

Initial treatment:

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Assessment of response to initial treatment:

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16896***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16927***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***12156***

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***16836***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16976***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

9305R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 794.25 | 25.00 | [a] Stelara [JC] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis:**

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15.

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot.

**Assessment of response to initial treatment:**

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

**Continuing treatment:**

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Swapping therapy:**

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

**Baseline measurements to determine response:**

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

**Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept):**

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

**Re-treatment (etanercept only):**

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy:**

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

**Note** For the next authority approval following this one, aim to conduct and submit the PASI assessment at approximately 4 weeks prior to when a new authority application is due to ensure uninterrupted supply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***18723***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The assessment of response to treatment must be provided in this application and documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**Authority Required**

***18898***

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment (Face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The assessment of response to treatment must be provided in this application and documented in the patient's medical records.

**Authority Required**

***17094***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment (Whole body)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Whole body) - treatment covering week 28 and onwards restrictions, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The assessment of response to treatment must be provided in this application and documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

**Authority Required**

***17000***

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment (Face, hand, foot)

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards restrictions, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The assessment of response to treatment must be provided in this application and documented in the patient's medical records.

### ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

12664M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 794.25 | 25.00 | [a] Stelara [JC] | [a] Wezlana [TN] |

## USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***16917***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 8 under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy (dosage, date of commencement and duration of therapy).

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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**Authority Required**

***16918***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a single dose to be administered at week 8 under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Authority Required**

***16828***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**

- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 8 under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

### ustekinumab 90 mg/mL injection, 1 mL syringe

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13273N | 1 | 0 | 0.00 | 986.28 | 25.00 | [a] Stelara [JC] | [a] Steqeyma [EW] |
| | | | | | | [a] Wezlana [TN] | |

## USTEKINUMAB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16899***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16937***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16885***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**

- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16910***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

| 10774C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 794.25 | 25.00 | [a] Stelara [JC] | [a] Wezlana [TN] |

**ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe**

| 14916C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 794.25 | 25.00 | [a] Steqeyma [EW] | [a] Wezlana [TN] |

## *Calcineurin inhibitors*

### CICLOSPORIN

**Caution** Where prescribed by a non-specialist prescriber, consult with a specialist medical practitioner on matters of diagnosis, choice of immunosuppressant and monitoring of immunosuppression in the patient.

**ciclosporin 10 mg capsule, 60**

| 8657P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *91.96 | 25.00 | Neoral 10 [NV] |

**ciclosporin 25 mg capsule, 30**

| 8658Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *60.34 | 25.00 | [a] APO-Ciclosporin [TX] | [a] CICLOSPORIN-WGR [WG] |
| | | | | | | [a] Neoral 25 [NV] | |

**ciclosporin 50 mg capsule, 30**

| 8659R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *110.04 | 25.00 | [a] APO-Ciclosporin [TX] | [a] CICLOSPORIN-WGR [WG] |
| | | | | | | [a] Neoral 50 [NV] | |

**ciclosporin 100 mg capsule, 30**

| 8660T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *214.04 | 25.00 | [a] APO-Ciclosporin [TX] | [a] CICLOSPORIN-WGR [WG] |
| | | | | | | [a] Neoral 100 [NV] | |

**ciclosporin 100 mg/mL oral liquid, 50 mL**

| 8661W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *701.04 | 25.00 | Neoral [NV] |

### CICLOSPORIN

**Caution** Where prescribed by a non-specialist prescriber, consult with a specialist medical practitioner on matters of diagnosis, choice of immunosuppressant and monitoring of immunosuppression in the patient.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ciclosporin 10 mg capsule, 60**

| 13999T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 3 | 0.00 | *172.32 | 25.00 | Neoral 10 [NV] |

**ciclosporin 25 mg capsule, 30**

| 13883Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 3 | 0.00 | *106.32 | 25.00 | [a] APO-Ciclosporin [TX] | [a] CICLOSPORIN-WGR [WG] |
| | | | | | | [a] Neoral 25 [NV] | |

**ciclosporin 50 mg capsule, 30**

| 13910D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 3 | 0.00 | *210.28 | 25.00 | [a] APO-Ciclosporin [TX] | [a] CICLOSPORIN-WGR [WG] |
| | | | | | | [a] Neoral 50 [NV] | |

**ciclosporin 100 mg capsule, 30**

| 13911E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 3 | 0.00 | *418.72 | 25.00 | [a] APO-Ciclosporin [TX] | [a] CICLOSPORIN-WGR [WG] |
| | | | | | | [a] Neoral 100 [NV] | |

**ciclosporin 100 mg/mL oral liquid, 50 mL**

| 14001X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 3 | 0.00 | *1,392.72 | 25.00 | Neoral [NV] |

## TACROLIMUS

**Caution** Careful monitoring of patients is mandatory.

### tacrolimus 500 microgram modified release capsule, 30

| 5299X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 53.49 | 25.00 | [a] ADVAGRAF XL [LQ] | [a] Tacrolimus XR Sandoz [SZ] |

### tacrolimus 500 microgram capsule, 100

| 8646C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 70.68 | 25.00 | [a] Pacrolim [AF] | [a] Pharmacor Tacrolimus 0.5 [CR] |
| | | | | | | [a] Prograf [LL] | [a] Tacrograf [RW] |
| | | | | | | [a] Tacrolimus Sandoz [SZ] | |

### tacrolimus 750 microgram capsule, 100

| 10870D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 99.96 | 25.00 | Tacrolimus Sandoz [SZ] |

### tacrolimus 1 mg modified release capsule, 60

| 5300Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 80.07 | 25.00 | [a] ADVAGRAF XL [LQ] | [a] Tacrolimus XR Sandoz [SZ] |

### tacrolimus 1 mg capsule, 100

| 8647D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 126.54 | 25.00 | [a] Pacrolim [AF] | [a] Pharmacor Tacrolimus 1 [CR] |
| | | | | | | [a] Prograf [LL] | [a] Tacrograf [RW] |
| | | | | | | [a] Tacrolimus Sandoz [SZ] | |

### tacrolimus 2 mg capsule, 100

| 10871E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 266.34 | 25.00 | Tacrolimus Sandoz [SZ] |

### tacrolimus 3 mg modified release capsule, 50

| 11914C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 386.64 | 25.00 | [a] ADVAGRAF XL [LQ] | [a] Tacrolimus XR Sandoz [SZ] |

### tacrolimus 5 mg modified release capsule, 30

| 5451X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 436.47 | 25.00 | [a] ADVAGRAF XL [LQ] | [a] Tacrolimus XR Sandoz [SZ] |

### tacrolimus 5 mg capsule, 50

| 8648E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 296.76 | 25.00 | [a] Pharmacor Tacrolimus 5 [CR] | [a] Prograf [LL] |
| | | | | | | [a] Tacrograf [RW] | [a] Tacrolimus Sandoz [SZ] |

## TACROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### tacrolimus 500 microgram modified release capsule, 30

| 13907Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *92.62 | 25.00 | [a] ADVAGRAF XL [LQ] | [a] Tacrolimus XR Sandoz [SZ] |

### tacrolimus 500 microgram capsule, 100

| 13908B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *127.64 | 25.00 | [a] Pacrolim [AF] | [a] Pharmacor Tacrolimus 0.5 [CR] |
| | | | | | | [a] Prograf [LL] | [a] Tacrograf [RW] |
| | | | | | | [a] Tacrolimus Sandoz [SZ] | |

### tacrolimus 750 microgram capsule, 100

| 14066H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *189.12 | 25.00 | Tacrolimus Sandoz [SZ] |

**tacrolimus 1 mg modified release capsule, 60**

| 13962W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *147.36 | 25.00 | [a] ADVAGRAF XL [LQ] | [a] Tacrolimus XR Sandoz [SZ] |

**tacrolimus 1 mg capsule, 100**

| 14070M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *243.72 | 25.00 | [a] Pacrolim [AF] | [a] Pharmacor Tacrolimus 1 [CR] |
| | | | | | | [a] Prograf [LL] | [a] Tacrograf [RW] |
| | | | | | | [a] Tacrolimus Sandoz [SZ] | |

**tacrolimus 2 mg capsule, 100**

| 13995N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *523.32 | 25.00 | Tacrolimus Sandoz [SZ] |

**tacrolimus 3 mg modified release capsule, 50**

| 13996P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *763.92 | 25.00 | [a] ADVAGRAF XL [LQ] | [a] Tacrolimus XR Sandoz [SZ] |

**tacrolimus 5 mg capsule, 50**

| 13909C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *584.16 | 25.00 | [a] Pharmacor Tacrolimus 5 [CR] | [a] Prograf [LL] |
| | | | | | | [a] Tacrograf [RW] | [a] Tacrolimus Sandoz [SZ] |

**tacrolimus 5 mg modified release capsule, 30**

| 14039X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 3 | 0.00 | *863.58 | 25.00 | [a] ADVAGRAF XL [LQ] | [a] Tacrolimus XR Sandoz [SZ] |

## *Sphingosine-1-phosphate (S1P) receptor modulators*

### ETRASIMOD

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15888***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***15926***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etrasimod 2 mg tablet, 28**

14601L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,429.64 | 25.00 | Velsipity [PF] |

## ETRASIMOD

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***15851***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy (dosage, date of commencement and duration of therapy).

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***15946***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***15887***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***15947***

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**etrasimod 2 mg tablet, 28**

14600K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 1,429.64 | 25.00 | Velsipity [PF] |

## FINGOLIMOD

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***16323***
Multiple sclerosis
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority Required (STREAMLINED)**
***16301***
Multiple sclerosis
Treatment Phase: Continuing treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**fingolimod 500 microgram capsule, 28**

5262Y
NP

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 449.44 | 25.00 | [a] AKM Fingolimod [RW] | [a] FILOSIR [NM] |
| | | | | | [a] Fingolimod Dr.Reddy's [RZ] | [a] Fingolimod Sandoz [SZ] |
| | | | | | [a] Fingolimod SUN [RA] | [a] Fingolimod-Teva [TB] |
| | | | | | [a] Fynod [AF] | [a] Gilenya [NV] |
| | | | | | [a] Pharmacor Fingolimod [CR] | |

## FINGOLIMOD

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***16325***
Multiple sclerosis
Treatment Phase: Initial treatment
**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**Population criteria:**

- Patient must weigh 40 kg or less.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority Required (STREAMLINED)**

***16346***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Population criteria:**

- Patient must weigh 40 kg or less.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

### fingolimod 250 microgram capsule, 28

| 11818B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 1,050.91 | 25.00 | Gilenya [NV] |

## OZANIMOD

**Note** Ensure that PBS-subsidy is approved for the 920 mcg strength prior to supply of this titration pack. It is advisable to only have the titration pack prescription dispensed at the same time as a prescription for the 920 mcg capsules, or where a supply of the 920 mcg capsules is already in existence (in the case of mid treatment dose interruption).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***14017***

Moderate to severe ulcerative colitis

Treatment Phase: Dose escalation occurring at initial treatment or re-initiation of treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### ozanimod 230 microgram capsule [4] (&) ozanimod 460 microgram capsule [3], 7

| 13251K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | ‡1 | 0 | 0.00 | 544.71 | 25.00 | Zeposia [BQ] |

## OZANIMOD

**Note** The initiation pack is intended for use at the commencement of treatment and for re-initiation of therapy following treatment interruption. The first prescription for the 920 microgram capsules should occur under the Initial treatment restriction. Subsequent prescriptions should then occur under the Continuing treatment restriction. If treatment interruption of more than 14 consecutive days occurs for reasons other than lack of efficacy, apply under the Continuing treatment restriction for each of the Initiation pack and 920 microgram capsules. If treatment interruption occurs within the first 14 days, or, for more than 7 consecutive doses between treatment Days 15 to 28, re-apply for an initiation pack under the 'Initial treatment' treatment phase.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16323***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority Required (STREAMLINED)**

***16301***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

### ozanimod 230 microgram capsule [4] (&) ozanimod 460 microgram capsule [3], 7

| 12278F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 544.71 | 25.00 | Zeposia [BQ] |

### ozanimod 920 microgram capsule, 28

| 12271W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 2,126.85 | 25.00 | Zeposia [BQ] |

## OZANIMOD

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***14002***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***13946***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ozanimod 920 microgram capsule, 28**

13269J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 2,126.85 | 25.00 | Zeposia [BQ] |

## OZANIMOD

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***13995***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**

- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14003***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14004***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***14005***

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### ozanimod 920 microgram capsule, 28

13271L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 2,126.85 | 25.00 | Zeposia [BQ] |

## SIPONIMOD

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16347***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of at least one of the brain/spinal cord; **OR**
- The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis supported by written certification, which is documented in the patient's medical records, from a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory, with/without assistance/support, **AND**
- Patient must have mild disability in at least 3 functional systems; **OR**
- Patient must have moderate disability in at least 1 functional system.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Functional systems referred to in this restriction are the: visual, brain stem, pyramidal, cerebellar, sensory, bowel/bladder and cerebral/cognitive systems.

Select a dose and pack size appropriate for the patient's CYP2C9 metabolising enzyme status.

**Note** There is no specific Medical Benefits Schedule item for CYP2C9 metabolising enzyme status testing.

**Authority Required (STREAMLINED)**

***16303***

Multiple sclerosis

Treatment Phase: Continuing treatment (including recommencement of treatment)

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must be ambulatory, with/without assistance/support, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**siponimod 250 microgram tablet, 12**

| 12172P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 223.51 | 25.00 | Mayzent [NV] |

**siponimod 1 mg tablet, 28**

| 14607T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 1,988.12 | 25.00 | Mayzent [NV] |

**siponimod 2 mg tablet, 28**

| 12158X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 2,126.85 | 25.00 | Mayzent [NV] |

### *Janus-associated kinase (JAK) inhibitors*

## BARICITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required (STREAMLINED)**

***14499***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**baricitinib 2 mg tablet, 28**

13689L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,032.23 | 25.00 | Olumiant [LY] |

**baricitinib 4 mg tablet, 28**

13702E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,032.23 | 25.00 | Olumiant [LY] |

## BARICITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the

necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***16725***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***14507***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**baricitinib 2 mg tablet, 28**

| 11442F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,032.23 | 25.00 | Olumiant [LY] |

**baricitinib 4 mg tablet, 28**

| 11443G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,032.23 | 25.00 | Olumiant [LY] |

## BARICITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18534***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18562***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18604***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18584***

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**baricitinib 2 mg tablet, 28**

| 11437Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 1,032.23 | 25.00 | Olumiant [LY] |

**baricitinib 4 mg tablet, 28**

| 11447L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 1,032.23 | 25.00 | Olumiant [LY] |

## DEUCRAVACITINIB

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17391***

Severe chronic plaque psoriasis

**Clinical criteria:**

- Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; **OR**
- Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; **OR**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate, **AND**
- The condition must have caused significant interference with quality of life, **AND**
- Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) apremilast.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; **OR**
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; **OR**
- Must be treated by a prescriber who is not any of the above, but where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types.

**Population criteria:**

- Patient must be at least 18 years of age.

For patients who do not demonstrate an adequate response to deucravacitinib, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

**deucravacitinib 6 mg tablet, 28**

| 13649J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 1,252.09 | 25.00 | Sotyktu [BQ] |

## TOFACITINIB

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

**Treatment cycles:**

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment Phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission:

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required (STREAMLINED)**

***17707***

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**tofacitinib 1 mg/mL oral liquid, 240 mL**

13738C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | 0.00 | 1,145.05 | 25.00 | Xeljanz [PF] |

## TOFACITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to

provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required (STREAMLINED)**

***14499***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**tofacitinib 5 mg tablet, 56**

| 13730P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,145.05 | 25.00 | Xeljanz [PF] |

## TOFACITINIB

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

**Treatment cycles:**

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment Phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a

treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission:

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17707***

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

### tofacitinib 5 mg tablet, 56

13737B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,145.05 | 25.00 | Xeljanz [PF] |

## TOFACITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***16725***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***14507***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tofacitinib 5 mg tablet, 56**

10511F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,145.05 | 25.00 | Xeljanz [PF] |

## TOFACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following

a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***11978***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***11886***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tofacitinib 5 mg tablet, 56**

| 11675L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,145.05 | 25.00 | Xeljanz [PF] |

## TOFACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***11883***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

**Population criteria:**

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** If a dose increase from tofacitinib 5mg twice daily to tofacitinib 10mg twice daily is required, tofacitinib 10mg may be authorised under the Balance of supply restriction to complete up to 24 weeks continuing treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority Required**

***12976***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** If a dose increase from tofacitinib 5mg twice daily to tofacitinib 10mg twice daily is required, tofacitinib 10mg may be authorised under this restriction to complete up to 24 weeks continuing treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tofacitinib 5 mg tablet, 56**

| 12557X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,145.05 | 25.00 | Xeljanz [PF] |

**tofacitinib 10 mg tablet, 56**

| 12589N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,889.76 | 25.00 | Xeljanz [PF] |

## TOFACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***14692***

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9431***

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tofacitinib 5 mg tablet, 56**

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## TOFACITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the

full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18534***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18562***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18604***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18584***

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**tofacitinib 5 mg tablet, 56**

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## TOFACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***11944***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***16392***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***11956***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9064***

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tofacitinib 5 mg tablet, 56**

11690G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 1,145.05 | 25.00 | Xeljanz [PF] |

## TOFACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***11940***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***11915***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***11975***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***11976***

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tofacitinib 5 mg tablet, 56**

| 12556W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 1,145.05 | 25.00 | Xeljanz [PF] |

**tofacitinib 10 mg tablet, 56**

| 12588M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 3 | 0.00 | 1,889.76 | 25.00 | Xeljanz [PF] |

## TOFACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for

PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***14670***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14655***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14662***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***12174***

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tofacitinib 5 mg tablet, 56**

13349N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 1,145.05 | 25.00 | Xeljanz [PF] |

## TOFACITINIB

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

**Treatment cycles:**

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment Phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission:

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***17745***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

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**Authority Required**

***17737***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Authority Required**

***17746***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority Required**

***12120***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**tofacitinib 1 mg/mL oral liquid, 240 mL**

13770R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 3 | 0.00 | 1,145.05 | 25.00 | Xeljanz [PF] |

## TOFACITINIB

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

**Treatment cycles:**

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment Phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers

may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission:

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***17745***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Authority Required**

***17737***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Authority Required**

***17746***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority Required**

***12120***

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**tofacitinib 5 mg tablet, 56**

13755Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 1,145.05 | 25.00 | Xeljanz [PF] |

## UPADACITINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications:

Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). *British Journal of Dermatology* 2014 December;171(6):1318-25.

Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. *The Journal of Allergy and Clinical Immunology* 2014 October;134(4):800-7

**Note** Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here:

https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index

**Note** The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication:

Fatumura M et al. *Journal of the American Academy of Dermatology* 2016; 64(2): 288-94

The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.

**Note** Dose changes subsequent to this authority application, whether they occur during an initial treatment or continuing treatment phase, may occur under the 'Dose change' treatment phase listing.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***12499***

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment with this drug of the whole body

**Clinical criteria:**

- Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**

- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- Patient must not have experienced an inadequate response to this therapy.

**Treatment criteria:**

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

**Population criteria:**

- Patient must be 12 years of age or older.

State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.

**Authority Required**

***12508***

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment with this drug of the face and/or hands

**Clinical criteria:**

- The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; **OR**
- The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- Patient must not have experienced an inadequate response to this therapy.

**Treatment criteria:**

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

**Population criteria:**

- Patient must be 12 years of age or older.

State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for:

(i) erythema,

(ii) oedema/papulation,

(iii) excoriation,

(iv) lichenification

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores.

The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.

**upadacitinib 15 mg modified release tablet, 28**

| 12828E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 4 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

**upadacitinib 30 mg modified release tablet, 28**

| 12836N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 4 | 0.00 | 1,983.58 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications:

Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). *British Journal of Dermatology* 2014 December;171(6):1318-25.

Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. *The Journal of Allergy and Clinical Immunology* 2014 October;134(4):800-7

**Note** Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here:

https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index

**Note** The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication:

Fatumura M et al. *Journal of the American Academy of Dermatology* 2016; 64(2): 288-94

The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.

**Note** Dose changes subsequent to this authority application, whether they occur during an initial treatment or continuing treatment phase, may occur under the 'Dose change' treatment phase listing.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***12493***

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment with this drug of the whole body

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the whole body, **AND**
- Patient must have achieved an adequate response prior to this first continuing treatment authority application; **OR**
- Patient must have maintained an adequate response to their most recent supply of this therapy for this PBS indication if this is any Continuing treatment authority application other than the first; **OR**
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application.

**Treatment criteria:**

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

For the purposes of this restriction, an adequate response to treatment is defined as:

(a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and

(b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

State each of the current EASI and DLQI scores for this authority application.

**Authority Required**

***12494***

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment with this drug of the face and/or hands

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the face/hands, **AND**
- Patient must have achieved an adequate response prior to this first continuing treatment authority application; **OR**

- Patient must have maintained an adequate response to their most recent supply of this therapy for this PBS indication if this is any Continuing treatment authority application other than the first; **OR**
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application.

**Treatment criteria:**

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as:

(a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or

(ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and

(b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes

**upadacitinib 15 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12831H | 1 | 5 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

**upadacitinib 30 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12829F | 1 | 5 | 0.00 | 1,983.58 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***12504***

Chronic severe atopic dermatitis

Treatment Phase: Dose change (increasing up to the 30 mg dose, or, decreasing back down to the 15 mg dose) - whole body, or, face/hands

**Treatment criteria:**

- Patient must not be undergoing each of: (i) commencing treatment through this treatment phase listing, (ii) treatment accessed through this treatment phase on more than 2 consecutive occasions, **AND**
- Patient must be undergoing existing PBS-subsidised treatment with this therapy where each of the following is true: (i) there is a change in daily dose, (ii) any remaining PBS repeat prescriptions for the strength that the patient is changing from, is marked as 'cancelled', **AND**
- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

**upadacitinib 15 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12835M | 1 | 3 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

**upadacitinib 30 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12827D | 1 | 3 | 0.00 | 1,983.58 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***13959***

Moderate to severe ulcerative colitis

Treatment Phase: Dose modification

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)], **AND**
- Patient must be undergoing existing PBS-subsidised treatment with this therapy.

**Note** Any further authority applications occurring immediately after access through this dose modification listing are not to occur through any of the following Treatment phase listings: (i) Balance of Supply, (ii) Initial Treatment.

**Note Dose modification**

Where the drug's Product Information indicates variable dosing regimens based on the individual's response/tolerance, apply under this listing to continue treatment with the new strength. Mark any remaining repeat prescriptions for the discontinued strength with the word 'cancelled'. This treatment phase listing recognises that a patient's optimal dose may not always be immediately apparent at the time of treatment initiation and therefore does not require confirmation of an objective, adequate response to the preceding supply of drug.

**upadacitinib 15 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13256Q | 1 | 1 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

**upadacitinib 30 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13265E | 1 | 1 | 0.00 | 1,983.58 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18896***

Severe Crohn disease

Treatment Phase: Extended induction period (optional) from weeks 12 to 24

**Clinical criteria:**

- Patient must must have experienced an inadequate therapeutic benefit following the initial 12-week induction period.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

### upadacitinib 30 mg modified release tablet, 28

13762H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 1,983.58 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required (STREAMLINED)**

***14499***

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

### upadacitinib 15 mg modified release tablet, 28

| 14125K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18671***

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18691***

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply - first continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### upadacitinib 15 mg modified release tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11979L | 1 | 5 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised

adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***14692***

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***9431***

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### upadacitinib 15 mg modified release tablet, 28

| 12621G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***11978***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***11886***

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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### upadacitinib 15 mg modified release tablet, 28

12648Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***14011***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** If a dose strength change is required, see 'Dose modification' treatment phase to continue treatment at a new dose strength.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***13958***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- The treatment must have been prescribed most recently through the Continuing treatment phase in a quantity which did not seek the full number available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions, **AND**
- The treatment must provide no more than the balance of 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**upadacitinib 15 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13250J | 1 | 5 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

**upadacitinib 30 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13249H | 1 | 5 | 0.00 | 1,983.58 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

**Treatment cycles:**

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Treatment phases:**

Initial treatment:

Applications for initial treatment should be made where:

- no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase; or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
- a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
- a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Continuing treatment:

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

Changing the prescribed biological medicine:

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

Baseline measurements to determine response:

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Balance of Supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***15140***

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***10434***

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### upadacitinib 15 mg modified release tablet, 28

13343G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18809***

Severe Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

**Clinical criteria:**

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend treatment beyond 24 weeks.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

**Authority Required**

***18810***

Severe Crohn disease

Treatment Phase: Continuing (maintenance) treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; **OR**
- The condition must have not met the improvements specified above due to the prescribed dose being too low - this authority application seeks higher dosing.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Authority Required**

***18897***

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Continuing (maintenance) treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

### upadacitinib 30 mg modified release tablet, 28

13746L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,983.58 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a

cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18809***

Severe Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

**Clinical criteria:**

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend treatment beyond 24 weeks.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

**Authority Required**

***18811***

Severe Crohn disease

Treatment Phase: Continuing (maintenance) treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

**Authority Required**

***18897***

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Continuing (maintenance) treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient restriction to complete 24 weeks of treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

### upadacitinib 15 mg modified release tablet, 28

| 13768P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

**Selecting the correct 'Treatment phase' listing to apply under:**

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment.

(ii) Apply through 'Initial 2 treatment' where one of the following occurs:

- PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing; or
- there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed; or
- there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed; or
- treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the

next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

**Baseline measurements to determine response:**

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18534***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18562***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18604***

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**

- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18584***

Severe active rheumatoid arthritis

Treatment Phase: Balance of supply - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### upadacitinib 15 mg modified release tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11989B | 1 | 3 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis:**

Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Swapping therapy:

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***11944***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***16392***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***11956***

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***9064***

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### upadacitinib 15 mg modified release tablet, 28

12624K

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

**Treatment cycles:**

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Prescribing under the correct 'Treatment phase' listing for the authority application:**

Initial treatment:

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

Continuing treatment:

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

Changing therapy:

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must

submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

Baseline measurements to determine response:

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***14670***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14655***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14662***

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***12174***

Ankylosing spondylitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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12625L

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## UPADACITINIB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at

the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***13999***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient - untreated with biological medicine)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***14014***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***13990***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***11976***

Moderate to severe ulcerative colitis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**upadacitinib 45 mg modified release tablet, 28**

13262B

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## UPADACITINIB

**Note PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS - TREATMENT CYCLES AND TREATMENT PHASES**

Where the term 'biological medicine' appears in notes and restrictions, it refers to pharmaceutical benefits listed specifically for the indication of: non-radiographic axial spondyloarthritis. Some listed pharmaceutical benefits are technically not biological medicines (e.g. Janus-kinase inhibitors), but for practical purposes, have been included under the broad term of 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine at any one time.

**Treatment cycles:**

A treatment cycle commences when the authority application for first PBS-subsidised biological medicine is approved for a given patient under the 'Initial 1' treatment phase. The treatment cycle continues until a fourth biological medicine fails to provide the patient with an adequate response. A new treatment cycle begins each time PBS subsidy is obtained through the 'Initial 3' treatment phase.

Within a treatment cycle, the same PBS-subsidised biological medicine must not be subsidised more than once where it has failed to provide the patient with an adequate response on any occasion that a response assessment is conducted.

Once biological medicines have failed to provide a patient with an adequate response 4 times (once with any biological medicine) within the same treatment cycle, the treatment cycle has been completed and the patient must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a completed treatment attempt.

Where there have been fewer than 4 inadequate responses with biological medicine therapy in a treatment cycle and there has been a break in therapy of less than 5 years, the patient may continue treatment within the same treatment cycle.

A patient who has had a break in therapy of more than 5 years may commence a new treatment cycle with up to 4 treatment attempts.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**Treatment phases:**

Initial treatment:

Applications for initial treatment should be made where:

- no prior PBS-subsidised biological medicine treatment has been prescribed - apply through the 'Initial 1 - New patient' treatment phase; or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy, but is prescribed an alternate biological medicine - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' [further details are under 'Changing the prescribed biological medicine' below]; or
- a patient is recommencing treatment following a break in PBS-subsidised therapy of less than 5 years - apply through the 'Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years' treatment phase (note that where there is both a change and recommencement after less than 5 years occurring simultaneously, Initial 2 is the correct treatment phase to apply through); or
- a patient is recommencing treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - apply through the 'Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years' treatment phase.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Continuing treatment:

For continuing PBS subsidy of biological medicine it is recommended that a patient be reviewed the month prior to when the continuing dose is due to ensure uninterrupted biological medicine supply.

Continuing PBS subsidy is available in quantities/repeats that provide up to 24 weeks of continuing treatment where an adequate response to the immediately preceding supply of treatment has been experienced.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the treatment will be deemed to have failed to provide an adequate response, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

Changing the prescribed biological medicine:

Once initial treatment with the first PBS-subsidised biological medicine is approved, an alternate biological medicine may be prescribed within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements. An authority application must be made under the 'Initial 2' treatment phase and must indicate the response to the preceding biological medicine in terms of whether the response was adequate or not. The prescription for the discontinued biological medicine must be marked as cancelled by the prescriber.

Baseline measurements to determine response:

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a patient untreated with biological medicines, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

A second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must occur through the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Balance of Supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words 'balance of supply'.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18249***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***15149***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

(a) a CRP measurement no greater than 10 mg per L; or

(b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

(a) the BASDAI score; and

(b) the C-reactive protein (CRP) level.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***15150***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and

(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***14217***

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### upadacitinib 15 mg modified release tablet, 28

13350P

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 3 | 0.00 | 1,203.55 | 25.00 | Rinvoq [VE] |

## UPADACITINIB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18817***

Severe Crohn disease

Treatment Phase: Initial 1 (induction treatment covering the first 12 weeks in a patient untreated with targeted therapy)

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must not have achieved an adequate response to a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of not achieving an adequate response to prior systemic therapy; **OR**
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below; **OR**
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(c) if applicable, details of intestinal inflammation marker/s; and

(d) if applicable, the CDAI score and the date of assessment; and

(e) the date of the most recent clinical assessment.

Evidence of not achieving an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 12 weeks of treatment with upadacitinib may be requested under the Balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18845***

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 12 weeks of treatment with upadacitinib may be requested under the Balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***18765***

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**

- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 while off treatment with targeted therapy; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; and evidence of flared disease while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and evidence of flared disease while off treatment with targeted therapy.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 12 weeks of treatment with upadacitinib may be requested under the Balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***18867***

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or extended induction restriction (Initial 1, Initial 2, Initial 3, or Extended induction period (optional) treatment), **AND**
- The treatment must provide no more than the balance of up to 12 weeks therapy available under Initial 1, 2 or 3 treatment restriction or the Extended induction period (optional) from weeks 12 to 24 treatment restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**upadacitinib 30 mg modified release tablet, 28**

15382N

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 2 | 0.00 | 1,983.58 | 25.00 | Rinvoq [VE] |

**upadacitinib 45 mg modified release tablet, 28**

| 13771T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 2,608.01 | 25.00 | Rinvoq [VE] |

## *Monoclonal antibodies*

## OFATUMUMAB

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16301***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

**ofatumumab 20 mg/0.4 mL injection, 0.4 mL pen device**

| 12641H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 2,231.82 | 25.00 | Kesimpta [NV] |

## OFATUMUMAB

**Note** The intent of this listing is to provide doses at weeks 0, 1 and 2. For treatment at week 4 and beyond, see the 'Continuing treatment' listing.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16323***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**ofatumumab 20 mg/0.4 mL injection, 0.4 mL pen device**

| 12642J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 0 | 0.00 | *6,476.73 | 25.00 | Kesimpta [NV] |

## VEDOLIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***15944***

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment with subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 1 (new patient); **OR**
- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years); **OR**
- Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years); **OR**
- Patient must have a concurrent authority application for the intravenous infusion for this condition under either Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

**Population criteria:**

- Patient must be at least 18 years of age.

Where two initial doses of vedolizumab (at weeks 0 and 2) are administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. The maximum listed quantity and 2 repeats should be requested to provide for weeks 6, 8, 10, 12, 14 and 16.

Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity with no repeats should be requested to provide for weeks 14 and 16.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12644L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 1,663.81 | 25.00 | Entyvio [TK] |

## VEDOLIZUMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**

***18877***

Severe Crohn disease

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, Continuing, or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment) with the subcutaneous form, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under either Initial 1, 2 or 3 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

### vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12620F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 1,663.81 | 25.00 | Entyvio [TK] |

## VEDOLIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**

***15943***

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; **OR**
- Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab intravenous form continuing treatment restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.

Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12639F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,663.81 | 25.00 | Entyvio [TK] |

## VEDOLIZUMAB

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

**Selecting the correct treatment phase listing when applying for authority approval:**

Initial treatment:

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

Continuing treatment:

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

Changing therapy:

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

Recommencement of treatment after a 5-year break in PBS-subsidised therapy:

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

Balance of supply:

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required**

***13237***

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply - subcutaneous form

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.

### vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

| 12647P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 1,663.81 | 25.00 | Entyvio [TK] |

## VEDOLIZUMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18879***

Severe Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

**Clinical criteria:**

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend beyond 24 weeks.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

**Authority Required**

***18904***

Severe Crohn disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; **OR**
- Patient must have demonstrated an adequate response to treatment with this drug (in any form).

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners must request sufficient quantity for up to 24 weeks of treatment under this restriction.

If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the continuing treatment period.

### vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12654B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 1,663.81 | 25.00 | Entyvio [TK] |

## VEDOLIZUMAB

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a

cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

**Initial 1 -** use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

**Initial 2 -** use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

**Initial 3 -** use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

**Transitioning from non-PBS supply commenced as a paediatric patient -** use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

**Continuing treatment -** use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

**Balance of supply -** use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

**Note** Special Pricing Arrangements apply.

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**Authority Required**

***18909***

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must not have achieved an adequate response to a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of not achieving an adequate response to prior systemic therapy; **OR**
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below; **OR**
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(c) if applicable, details of intestinal inflammation marker/s; and

(d) if applicable, the CDAI score and the date of assessment; and

(e) the date of the most recent clinical assessment.

Evidence of not achieving an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

**Authority Required**

***18860***

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to

treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority Required**

***18878***

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 while off treatment with targeted therapy; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; and evidence of flared disease while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and evidence of flared disease while off treatment with targeted therapy.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

**Population criteria:**

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices**

12638E

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 1,663.81 | 25.00 | Entyvio [TK] |

## *Mammalian target of rapamycin (mTOR) kinase inhibitors*

### EVEROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**everolimus 250 microgram tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8840G | 1 | 3 | 0.00 | 175.74 | 25.00 | [a] Certican [NV] | [a] Everocan [CR] |

**everolimus 500 microgram tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8841H | 1 | 3 | 0.00 | 299.80 | 25.00 | [a] Certican [NV] | [a] Everocan [CR] |

**everolimus 750 microgram tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8842J | 2 | 3 | 0.00 | *880.70 | 25.00 | [a] Certican [NV] | [a] Everocan [CR] |

**everolimus 1 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9352F | 2 | 3 | 0.00 | *1,171.14 | 25.00 | [a] Certican [NV] | [a] Everocan [CR] |

## EVEROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**everolimus 750 microgram tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14040Y | 4 | 3 | 0.00 | *1,752.04 | 25.00 | [a] Certican [NV] | [a] Everocan [CR] |

**everolimus 1 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13941R | 4 | 3 | 0.00 | *2,322.28 | 25.00 | [a] Certican [NV] | [a] Everocan [CR] |

## SIROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**sirolimus 500 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8984W | 1 | 3 | 0.00 | 331.08 | 25.00 | Rapamune [PF] |

**sirolimus 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8724E | 1 | 3 | 0.00 | 652.78 | 25.00 | Rapamune [PF] |

**sirolimus 1 mg/mL oral liquid, 60 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8725F | ‡1 | 3 | 0.00 | 515.33 | 25.00 | Rapamune [PF] |

**sirolimus 2 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8833X | 1 | 3 | 0.00 | 1,292.00 | 25.00 | Rapamune [PF] |

## SIROLIMUS

**Caution** Careful monitoring of patients is mandatory.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**sirolimus 500 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13860L | 2 | 3 | 0.00 | *652.80 | 25.00 | Rapamune [PF] |

**sirolimus 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14072P | 2 | 3 | 0.00 | *1,296.20 | 25.00 | Rapamune [PF] |

**sirolimus 1 mg/mL oral liquid, 60 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13885T | ‡2 | 3 | 0.00 | *1,021.30 | 25.00 | Rapamune [PF] |

**sirolimus 2 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13886W | 2 | 3 | 0.00 | *2,552.48 | 25.00 | Rapamune [PF] |

***Complement inhibitors***

## AVACOPAN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15894***

Anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must be severe granulomatosis with polyangiitis; **OR**
- The condition must be severe microscopic polyangiitis, **AND**
- The condition must be active at the time of the first prescription for this drug per treatment cycle, **AND**
- Patient must have ANCA associated vasculitis that is either: (i) organ-threatening, (ii) life-threatening disease, **AND**
- Patient must be undergoing concomitant therapy with at least another drug therapy as part of a regimen specified in this drug's approved Product Information, **AND**
- Patient must not receive more than 12 months of PBS-subsidised treatment with this drug per induction.

A prescriber may apply for more than one induction treatment for their patient

**avacopan 10 mg capsule, 180**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14605Q | 1 | 5 | 0.00 | 8,622.02 | 25.00 | Tavneos [CS] |

## IPTACOPAN

**Caution** This drug increases the risk of encapsulated bacterial infections.

Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17695***

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment (new patient)

**Clinical criteria:**

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have PNH granulocyte clone size equal to or greater than 10% within the last 3 months, **AND**
- Patient must have experienced an inadequate response/intolerance to either: (i) Complement 5 (C5) inhibitor, (ii) pegcetacoplan, **AND**
- Patient must have received treatment with at least one complement inhibitor for at least 3 months before initiating treatment with this drug unless intolerance of severity necessitating permanent treatment withdrawal had occurred, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

**Authority Required**

***17666***

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised eculizumab post pregnancy or from PBS-subsidised Complement 5 (C5) inhibitor for reasons other than post pregnancy

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - (initial 3) switching from PBS-subsidised pegcetacoplan or iptacopan for pregnancy (induction doses)' criteria; **OR**
- Patient must have received prior PBS-subsidised treatment with at least one C5 inhibitor and must be returning to iptacopan treatment for reasons other than post pregnancy, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

Patients may qualify under this treatment phase more than once.

**Authority Required**

***17676***

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided on the first continuing authority application:

(i) Haemoglobin (g/L)

(ii) Platelets (x$10^9$/L)

(iii) White Cell Count (x$10^9$/L)

(iv) Reticulocytes (x$10^9$/L)

(v) Neutrophils (x$10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

### Iptacopan 200 mg capsule, 56

15064W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 38,989.58 | 25.00 | Fabhalta [NV] |

## *Dihydroorotate dehydrogenase (DHODH) inhibitors*

## LEFLUNOMIDE

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Restricted benefit**

***13771***

Severe active psoriatic arthritis

**Clinical criteria:**

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; **OR**
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

### leflunomide 10 mg tablet, 30

5449T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP 1 | 5 | 0.00 | 24.95 | 25.00 | [a] APO-LEFLUNOMIDE [TX] | [a] Arava [SW] |
| | | | | | [a] Ataris 10 [AF] | [a] Leflunomide generichealth [HQ] |
| | | | | | [a] Leflunomide Sandoz [SZ] | [a] LEFLUNOMIDE-WGR [WG] |

### leflunomide 20 mg tablet, 30

5450W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP 1 | 5 | 0.00 | 30.47 | 25.00 | [a] APO-LEFLUNOMIDE [TX] | [a] Arava [SW] |
| | | | | | [a] Ataris 20 [AF] | [a] Leflunomide generichealth [HQ] |
| | | | | | [a] Leflunomide Sandoz [SZ] | [a] LEFLUNOMIDE-WGR [WG] |

## LEFLUNOMIDE

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Restricted benefit**

***13753***

Severe active rheumatoid arthritis

**Clinical criteria:**

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; **OR**
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

**leflunomide 10 mg tablet, 30**

| 8374R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 24.95 | 25.00 | [a] APO-LEFLUNOMIDE [TX] | [a] Arava [SW] |
| | | | | | | [a] Ataris 10 [AF] | [a] Leflunomide generichealth [HQ] |
| | | | | | | [a] Leflunomide Sandoz [SZ] | [a] LEFLUNOMIDE-WGR [WG] |
| | | | | | | [a] Lunava 10 [RW] | |

**leflunomide 20 mg tablet, 30**

| 8375T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 30.47 | 25.00 | [a] APO-LEFLUNOMIDE [TX] | [a] Arava [SW] |
| | | | | | | [a] Ataris 20 [AF] | [a] Leflunomide generichealth [HQ] |
| | | | | | | [a] Leflunomide Sandoz [SZ] | [a] LEFLUNOMIDE-WGR [WG] |
| | | | | | | [a] Lunava 20 [RW] | |

## LEFLUNOMIDE

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Restricted benefit**

***14942***

Severe active rheumatoid arthritis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; **OR**
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

**leflunomide 10 mg tablet, 30**

| 13940Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *35.54 | 25.00 | [a] APO-LEFLUNOMIDE [TX] | [a] Arava [SW] |
| | | | | | | [a] Ataris 10 [AF] | [a] Leflunomide generichealth [HQ] |
| | | | | | | [a] Leflunomide Sandoz [SZ] | [a] LEFLUNOMIDE-WGR [WG] |
| | | | | | | [a] Lunava 10 [RW] | |

**leflunomide 20 mg tablet, 30**

| 14069L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *46.58 | 25.00 | [a] APO-LEFLUNOMIDE [TX] | [a] Arava [SW] |
| | | | | | | [a] Ataris 20 [AF] | [a] Leflunomide generichealth [HQ] |
| | | | | | | [a] Leflunomide Sandoz [SZ] | [a] LEFLUNOMIDE-WGR [WG] |
| | | | | | | [a] Lunava 20 [RW] | |

## LEFLUNOMIDE

**Caution** Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Restricted benefit**

***14941***

Severe active psoriatic arthritis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; **OR**

- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

**leflunomide 10 mg tablet, 30**

| 14068K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *35.54 | 25.00 | [a] APO-LEFLUNOMIDE [TX] | [a] Arava [SW] |
| | | | | | | [a] Ataris 10 [AF] | [a] Leflunomide generichealth [HQ] |
| | | | | | | [a] Leflunomide Sandoz [SZ] | [a] LEFLUNOMIDE-WGR [WG] |

**leflunomide 20 mg tablet, 30**

| 13998R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *46.58 | 25.00 | [a] APO-LEFLUNOMIDE [TX] | [a] Arava [SW] |
| | | | | | | [a] Ataris 20 [AF] | [a] Leflunomide generichealth [HQ] |
| | | | | | | [a] Leflunomide Sandoz [SZ] | [a] LEFLUNOMIDE-WGR [WG] |

## TERIFLUNOMIDE

**Caution** Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception.

Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16323***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority Required (STREAMLINED)**

***16315***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**teriflunomide 14 mg tablet, 28**

| 2898M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 97.94 | 25.00 | [a] APO-TERIFLUNOMIDE [TX] | [a] Pharmacor Teriflunomide [CR] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2898M | | | | | | [a] TERIFLAGIO [RW] | [a] Teriflunomide Dr.Reddy's [RZ] |
| | | | | | | [a] Teriflunomide GH [GQ] | [a] Teriflunomide Sandoz [SZ] |
| | | | | | | [a] Terimide [AF] | |

## *Other immunosuppressants*

## AZATHIOPRINE

### azathioprine 25 mg tablet, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2688L | | | | | | | |
| NP | 1 | 5 | 0.00 | 22.50 | 24.04 | [a] APO-Azathioprine [TX] | [a] Azathioprine Sandoz [SZ] |
| | | | | | | [a] AZATHIOPRINE-WGR [WG] | |
| | | | [B]5.82 | 28.32 | 24.04 | [a] Imuran [AS] | |

### azathioprine 50 mg tablet, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2687K | | | | | | | |
| NP | 1 | 5 | 0.00 | 28.22 | 25.00 | [a] APO-Azathioprine [TX] | [a] Azapin [RW] |
| | | | | | | [a] Azathioprine Sandoz [SZ] | [a] AZATHIOPRINE-WGR [WG] |
| | | | | | | [a] Imazan [ZS] | [a] Thioprine 50 [AF] |
| | | | [B]5.82 | 34.04 | 25.00 | [a] Imuran [AS] | |

## DIMETHYL FUMARATE

**Authority Required (STREAMLINED)**

***16315***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

### dimethyl fumarate 120 mg enteric capsule, 14

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2943X | | | | | | | |
| NP | 2 | 0 | 0.00 | *207.72 | 25.00 | [a] APO-DIMETHYL FUMARATE [XT] | [a] Dimethyl Fumarate Sandoz [SZ] |
| | | | | | | [a] Pharmacor Dimethyl Fumarate [CR] | [a] Tecfidera [BD] |

### dimethyl fumarate 240 mg enteric capsule, 56

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2966D | | | | | | | |
| NP | 1 | 5 | 0.00 | 274.42 | 25.00 | [a] APO-DIMETHYL FUMARATE [XT] | [a] Dimethyl Fumarate Sandoz [SZ] |
| | | | | | | [a] Pharmacor Dimethyl Fumarate [CR] | [a] Tecfidera [BD] |
| | | | | | | [a] Trazent [AF] | |

## DIMETHYL FUMARATE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16323***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**dimethyl fumarate 120 mg enteric capsule, 14**

| 2896K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *207.72 | 25.00 | [a] APO-DIMETHYL FUMARATE [XT]<br>[a] Pharmacor Dimethyl Fumarate [CR] | [a] Dimethyl Fumarate Sandoz [SZ]<br>[a] Tecfidera [BD] |

## DIROXIMEL FUMARATE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16323***

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority Required (STREAMLINED)**

***16315***

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner in consultation with a specialist physician.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**diroximel fumarate 231 mg enteric capsule, 120**

| 13059H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 695.45 | 25.00 | Vumerity [BD] |

## METHOTREXATE

### methotrexate 2.5 mg tablet, 30

| 1622J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.45 | 20.99 | [a] ARX-Methotrexate [XT] | [a] Chexate [OX] |
| | | | | | | [a] Methoblastin [PF] | |

### methotrexate 10 mg tablet, 15

| 2272N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 24.86 | 25.00 | [a] ARX-Methotrexate [XT] | [a] Chexate [OX] |
| | | | | | | [a] Methoblastin [PF] | |

### methotrexate 10 mg tablet, 10

| 14643Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.36 | 22.90 | [a] Chexate [OX] | [a] Methoblastin [PF] |

## METHOTREXATE

**Restricted benefit**

***5648***

Patients requiring doses greater than 20 mg per week

### methotrexate 10 mg tablet, 50

| 1623K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 49.35 | 25.00 | [a] ARX-Methotrexate [XT] | [a] Chexate [OX] |
| | | | | | | [a] Methoblastin [PF] | |

## METHOTREXATE

**Authority Required (STREAMLINED)**

***7488***

Severe active rheumatoid arthritis

**Clinical criteria:**

- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

**Authority Required (STREAMLINED)**

***7518***

Severe psoriasis

**Clinical criteria:**

- The condition must not have adequately responded to topical treatment, **AND**
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

### methotrexate 7.5 mg/0.15 mL injection, 0.15 mL syringe

| 11275K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *89.44 | 25.00 | Trexject [LM] |

### methotrexate 10 mg/0.2 mL injection, 0.2 mL syringe

| 11283W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *89.44 | 25.00 | Trexject [LM] |

### methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe

| 11268C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *89.44 | 25.00 | Trexject [LM] |

### methotrexate 20 mg/0.4 mL injection, 0.4 mL syringe

| 11288D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *89.44 | 25.00 | Trexject [LM] |

### methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe

| 11295L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *89.44 | 25.00 | Trexject [LM] |

## METHOTREXATE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15068***

Severe active juvenile idiopathic arthritis

**Clinical criteria:**

- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

**methotrexate 7.5 mg/0.15 mL injection, 0.15 mL syringe**

| 14091P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *89.44 | 25.00 | Trexject [LM] |

**methotrexate 10 mg/0.2 mL injection, 0.2 mL syringe**

| 14089M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *89.44 | 25.00 | Trexject [LM] |

**methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe**

| 14102F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *89.44 | 25.00 | Trexject [LM] |

**methotrexate 20 mg/0.4 mL injection, 0.4 mL syringe**

| 14097Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *89.44 | 25.00 | Trexject [LM] |

**methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe**

| 14103G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *89.44 | 25.00 | Trexject [LM] |

## PIRFENIDONE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17356***

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**pirfenidone 801 mg tablet, 90**

| 11410M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 346.23 | 25.00 | [a] ARX-Pirfenidone [XW] | [a] Pirfenidet [AF] |
| | | | | | | [a] Pirfenidone Ameda [XT] | [a] Pirfenidone Dr.Reddy's [RZ] |
| | | | | | | [a] Pirfenidone Sandoz [SZ] | |

## PIRFENIDONE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17320***

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

**Clinical criteria:**

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must not have had an acute respiratory infection at the time of FVC measurement, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**

- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***17277***

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or recommencement of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types, **AND**
- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***17329***

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types, **AND**

- Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis, **AND**
- Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**pirfenidone 267 mg tablet, 90**

| 11406H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *346.23 | 25.00 | [a] ARX-Pirfenidone [XW] | [a] Pirfenidet [AF] |
| | | | | | | [a] Pirfenidone Ameda [XT] | [a] Pirfenidone Dr.Reddy's [RZ] |
| | | | | | | [a] Pirfenidone Sandoz [SZ] | |

# MUSCULO-SKELETAL SYSTEM

## ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

### ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

#### *Acetic acid derivatives and related substances*

### DICLOFENAC

**diclofenac sodium 25 mg enteric tablet, 50**

| 1299J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 2 | 3 | 0.00 | *19.84 | 21.38 | [a] Clonac 25 [RW] | [a] Diclofenac Sandoz [SZ] |
| | | | | | | [a] DICLOFENAC-WGR [WG] | [a] Fenac EC [AL] |
| | | | [B]9.44 | 29.28 | 21.38 | [a] Voltaren 25 [NV] | |

**diclofenac sodium 25 mg enteric tablet, 50**

| 5076E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 2 | 0 | 0.00 | *19.84 | 21.38 | [a] Clonac 25 [RW] | [a] Diclofenac Sandoz [SZ] |
| | | | | | | [a] DICLOFENAC-WGR [WG] | [a] Fenac EC [AL] |
| | | | [B]9.44 | 29.28 | 21.38 | [a] Voltaren 25 [NV] | |

**diclofenac sodium 50 mg enteric tablet, 50**

| 1300K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 3 | 0.00 | 17.10 | 18.64 | [a] Clonac 50 [RW] | [a] Diclofenac Sandoz [SZ] |
| | | | | | | [a] DICLOFENAC-WGR [WG] | [a] Fenac EC [AL] |
| | | | [B]9.73 | 26.83 | 18.64 | [a] Voltaren 50 [NV] | |

**diclofenac sodium 50 mg enteric tablet, 50**

| 5077F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Clonac 50 [RW] | [a] Diclofenac Sandoz [SZ] |
| | | | | | | [a] DICLOFENAC-WGR [WG] | [a] Fenac EC [AL] |
| | | | [B]9.73 | 26.83 | 18.64 | [a] Voltaren 50 [NV] | |

### INDOMETACIN

**indometacin 100 mg suppository, 20**

| 2757D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 2 | 3 | 0.00 | *27.92 | 25.00 | Indocid [AS] |

**indometacin 100 mg suppository, 20**

| 5128X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | 0 | 0.00 | *27.92 | 25.00 | Indocid [AS] |

### INDOMETACIN

**Restricted benefit**

***6214***

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

***6283***

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**indometacin 25 mg capsule, 50**

| 2454E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *23.90 | 25.00 | [a] Arthrexin [AF] | |
| | | | [B]1.82 | *25.72 | 25.00 | [a] Indocid [AS] | |

## INDOMETACIN

**Restricted benefit**

***6282***

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

***6256***

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**indometacin 25 mg capsule, 50**

| 5126T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 2 | 0 | 0.00 | *23.90 | 25.00 | [a] Arthrexin [AF] | |
| | | | [B]1.82 | *25.72 | 25.00 | [a] Indocid [AS] | |

### *Oxicams*

## MELOXICAM

**Note** Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

**Restricted benefit**

***4962***

Osteoarthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain; (b) soft tissue injury; (c) arthrosis without an inflammatory component.

**Restricted benefit**

***4907***

Rheumatoid arthritis

**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain; (b) soft tissue injury; (c) arthrosis without an inflammatory component.

**meloxicam 7.5 mg tablet, 30**

| 8561N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 17.70 | 19.24 | [a] APX-Meloxicam [TY] | [a] CIPLA MELOXICAM 7.5 [LR] |
| | | | | | | [a] MELOBIC [RF] | [a] Meloxibell [GQ] |
| | | | | | | [a] Meloxicam Sandoz [SZ] | [a] Meloxicam Viatris [AL] |
| | | | | | | [a] MELOXICAM-WGR [WG] | [a] Movalis 7.5 [RW] |
| | | | | | | [a] Moxicam 7.5 [AF] | |
| | | | [B]2.80 | 20.50 | 19.24 | [a] Mobic [BY] | |

**meloxicam 7.5 mg capsule, 30**

| 8887R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 17.70 | 19.24 | [a] APO-Meloxicam [TX] | [a] MELOBIC [RF] |
| | | | | | | [a] MELOXICAM-WGR [WG] | [a] Movalis 7.5 [RW] |
| | | | | | | [a] Moxicam [AF] | |
| | | | [B]2.80 | 20.50 | 19.24 | [a] Mobic [BY] | |

## MELOXICAM

**Note** Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

**Restricted benefit**

***4962***
Osteoarthritis
**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain; (b) soft tissue injury; (c) arthrosis without an inflammatory component.

**Restricted benefit**
***4907***
Rheumatoid arthritis
**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain; (b) soft tissue injury; (c) arthrosis without an inflammatory component.

**meloxicam 15 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8562P | | | | | | | |
| NP | 1 | 3 | 0.00 | 18.40 | 19.94 | [a] APX-Meloxicam [TY] | [a] CIPLA MELOXICAM 15 [LR] |
| | | | | | | [a] MELOBIC [RF] | [a] Meloxibell [GQ] |
| | | | | | | [a] Meloxicam Sandoz [SZ] | [a] Meloxicam Viatris [AL] |
| | | | | | | [a] MELOXICAM-WGR [WG] | [a] Movalis 15 [RW] |
| | | | | | | [a] Moxicam 15 [AF] | |
| | | | [B]2.83 | 21.23 | 19.94 | [a] Mobic [BY] | |

**meloxicam 15 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8888T | | | | | | | |
| NP | 1 | 3 | 0.00 | 18.40 | 19.94 | [a] APO-Meloxicam [TX] | [a] MELOBIC [RF] |
| | | | | | | [a] MELOXICAM-WGR [WG] | [a] Movalis 15 [RW] |
| | | | | | | [a] Moxicam [AF] | |

## PIROXICAM

**Restricted benefit**
***6214***
Chronic arthropathies (including osteoarthritis)
**Clinical criteria:**

- The condition must have an inflammatory component.

**piroxicam 10 mg capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1897W | | | | | | |
| NP | 1 | 3 | 0.00 | 18.75 | 20.29 | APO-Piroxicam [TX] |

**piroxicam 10 mg capsule, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5203W | | | | | | |
| DP | 1 | 0 | 0.00 | 18.75 | 20.29 | APO-Piroxicam [TX] |

**piroxicam 20 mg capsule, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1898X | | | | | | |
| NP | 1 | 3 | 0.00 | 17.56 | 19.10 | APO-Piroxicam [TX] |

**piroxicam 20 mg capsule, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5204X | | | | | | |
| DP | 1 | 0 | 0.00 | 17.56 | 19.10 | APO-Piroxicam [TX] |

### *Propionic acid derivatives*

## IBUPROFEN

**ibuprofen 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3192B | | | | | | | |
| NP MW | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Ibuprofen 400 [TX] | [a] WGR-IBUPROFEN 400 [WG] |
| | | | [B]2.34 | 19.44 | 18.64 | [a] Brufen [GO] | |

**ibuprofen 400 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5124Q | | | | | | | |
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Ibuprofen 400 [TX] | [a] WGR-IBUPROFEN 400 [WG] |
| | | | [B]2.34 | 19.44 | 18.64 | [a] Brufen [GO] | |

## IBUPROFEN

**Restricted benefit**

***6214***

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

***6283***

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**ibuprofen 400 mg tablet, 30**

| 3190X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 3 | 3 | 0.00 | *22.59 | 24.13 | [a] APO-Ibuprofen 400 [TX] | [a] WGR-IBUPROFEN 400 [WG] |
| | | | [B]7.02 | *29.61 | 24.13 | [a] Brufen [GO] | |

## IBUPROFEN

**Restricted benefit**

***6282***

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

***6256***

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**ibuprofen 400 mg tablet, 30**

| 5123P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 3 | 0 | 0.00 | *22.59 | 24.13 | [a] APO-Ibuprofen 400 [TX] | [a] WGR-IBUPROFEN 400 [WG] |
| | | | [B]7.02 | *29.61 | 24.13 | [a] Brufen [GO] | |

## NAPROXEN

**Restricted benefit**

***6214***

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

***6283***

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**naproxen 250 mg tablet, 50**

| 1674D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *23.62 | 25.00 | Naprosyn [IX] |

**naproxen 750 mg modified release tablet, 28**

| 1614Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 19.14 | 20.68 | [a] Proxen SR 750 [IY] | |
| | | | [B]2.30 | 21.44 | 20.68 | [a] Naprosyn SR750 [IX] | |

**naproxen 1 g modified release tablet, 28**

| 1615B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 20.72 | 22.26 | [a] Proxen SR 1000 [IY] | |
| | | | [B]2.29 | 23.01 | 22.26 | [a] Naprosyn SR1000 [IX] | |

## NAPROXEN

**Authority Required (STREAMLINED)**

***4159***

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component, **AND**

- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**Authority Required (STREAMLINED)**

***4124***

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease, **AND**
- Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

### naproxen 125 mg/5 mL oral liquid, 474 mL

| 1658G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 3 | 0.00 | 121.58 | 25.00 | Phebra Naproxen Suspension [FF] |

## NAPROXEN

**Restricted benefit**

***6463***

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

***6471***

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

### naproxen sodium 550 mg tablet, 50

| 1795L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 19.75 | 21.29 | [a] Crysanal [IY] | |
| | | | [B]2.77 | 22.52 | 21.29 | [a] Anaprox 550 [IX] | |

## NAPROXEN

**Restricted benefit**

***6282***

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Restricted benefit**

***6256***

Bone pain

**Clinical criteria:**

- The condition must be due to malignant disease.

### naproxen 250 mg tablet, 50

| 5176K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | 0 | 0.00 | *23.62 | 25.00 | Naprosyn [IX] |

### naproxen 750 mg modified release tablet, 28

| 5178M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 19.14 | 20.68 | [a] Proxen SR 750 [IY] | |
| | | | [B]2.30 | 21.44 | 20.68 | [a] Naprosyn SR750 [IX] | |

### naproxen 1 g modified release tablet, 28

| 5179N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 20.72 | 22.26 | [a] Proxen SR 1000 [IY] | |
| | | | [B]2.29 | 23.01 | 22.26 | [a] Naprosyn SR1000 [IX] | |

## NAPROXEN

**Restricted benefit**

***6368***

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

- The condition must have an inflammatory component.

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**
***6387***
Bone pain
**Clinical criteria:**

- The condition must be due to malignant disease.

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**naproxen sodium 550 mg tablet, 50**

| 5186Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 19.75 | 21.29 | [a] Crysanal [IY] | |
| | | | [B]2.77 | 22.52 | 21.29 | [a] Anaprox 550 [IX] | |

## *Fenamates*

### MEFENAMIC ACID

**Restricted benefit**
***6229***
Dysmenorrhoea
**Restricted benefit**
***6213***
Menorrhagia

**mefenamic acid 250 mg capsule, 50**

| 1824B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 19.16 | 20.70 | [a] FEMIN [XT] | |
| | | | [B]1.54 | 20.70 | 20.70 | [a] Ponstan [PF] | |

## *Coxibs*

### CELECOXIB

**Restricted benefit**
***4962***
Osteoarthritis
**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain; (b) soft tissue injury; (c) arthrosis without an inflammatory component.

**Restricted benefit**
***4907***
Rheumatoid arthritis
**Clinical criteria:**

- The treatment must be for symptomatic treatment.

**Note** The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain; (b) soft tissue injury; (c) arthrosis without an inflammatory component.

**celecoxib 100 mg capsule, 60**

| 8439E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 18.60 | 20.14 | [a] APX-Celecoxib [TW] | [a] Blooms Celecoxib [BG] |
| | | | | | | [a] Celaxib [AF] | [a] Celebrex [GO] |
| | | | | | | [a] Celecoxib GH [GQ] | [a] Celecoxib Sandoz [SZ] |
| | | | | | | [a] CELECOXIB-WGR [WG] | [a] Celexi [RW] |

**celecoxib 200 mg capsule, 30**

| 8440F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 18.60 | 20.14 | [a] APX-Celecoxib [TW] | [a] Blooms Celecoxib [BG] |
| | | | | | | [a] Celaxib [AF] | [a] Celebrex [GO] |
| | | | | | | [a] Celecoxib GH [GQ] | [a] Celecoxib Sandoz [SZ] |
| | | | | | | [a] CELECOXIB-WGR [WG] | [a] Celexi [RW] |

# SPECIFIC ANTIRHEUMATIC AGENTS

## *Quinolines*

## HYDROXYCHLOROQUINE

**hydroxychloroquine sulfate 200 mg tablet, 100**

| 1512N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 28.00 | 25.00 | [a] APO- Hydroxychloroquine [TX] | [a] Hequinel [RW] |
| | | | | | | [a] Hydroxychloroquine GH [GQ] | [a] Plaquenil [SW] |

### *Gold preparations*

## AURANOFIN

**Caution** Regular blood and urine checks are essential.

**Restricted benefit**

***15956***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**auranofin 3 mg tablet, 60**

| 1095P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 161.99 | 25.00 | Ridaura [GH] |

**auranofin 3 mg capsule, 60**

| 2022K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 885.48 | 25.00 | Ridaura [BZ] |

### *Penicillamine and similar agents*

## PENICILLAMINE

**Caution** Regular blood and urine checks are essential.

**Restricted benefit**

***15956***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**penicillamine 125 mg tablet, 100**

| 2721F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 82.07 | 25.00 | D-Penamine [AL] |

**penicillamine 250 mg tablet, 100**

| 2838J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 105.95 | 25.00 | D-Penamine [AL] |

## PENICILLAMINE

**Caution** Regular blood and urine checks are essential.

**Restricted benefit**

***16078***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**penicillamine 125 mg tablet, 100**

| 13458H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *151.56 | 25.00 | D-Penamine [AL] |

**penicillamine 250 mg tablet, 100**

| 13425N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 1 | 0.00 | *201.70 | 25.00 | D-Penamine [AL] |

# MUSCLE RELAXANTS

## MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

### *Other centrally acting agents*

## BACLOFEN

**baclofen 10 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2729P | | | | | | | |
| NP | 1 | 5 | 0.00 | 22.96 | 24.50 | [a] APO-Baclofen [TX] | [a] Clofen 10 [AF] |
| | | | | | | [a] Lioresal 10 [NV] | [a] Stelax 10 [RW] |

**baclofen 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2730Q | | | | | | | |
| NP | 1 | 5 | 0.00 | 33.17 | 25.00 | [a] APO-Baclofen [TX] | [a] Clofen 25 [AF] |
| | | | | | | [a] Lioresal 25 [NV] | [a] Stelax 25 [RW] |

## BACLOFEN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**baclofen 10 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13522Q | | | | | | | |
| NP | 2 | 5 | 0.00 | *31.56 | 25.00 | [a] APO-Baclofen [TX] | [a] Clofen 10 [AF] |
| | | | | | | [a] Lioresal 10 [NV] | [a] Stelax 10 [RW] |

**baclofen 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13359D | | | | | | | |
| NP | 2 | 5 | 0.00 | *51.98 | 25.00 | [a] APO-Baclofen [TX] | [a] Clofen 25 [AF] |
| | | | | | | [a] Lioresal 25 [NV] | [a] Stelax 25 [RW] |

## MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS

### *Dantrolene and derivatives*

## DANTROLENE

**Restricted benefit**

***6359***

Chronic spasticity

**dantrolene sodium hemiheptahydrate 25 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1779P | | | | | | |
| NP | 1 | 2 | 0.00 | 159.09 | 25.00 | Dantrium [PF] |

# ANTIGOUT PREPARATIONS

## ANTIGOUT PREPARATIONS

### *Preparations inhibiting uric acid production*

## ALLOPURINOL

**Note** The dose should be adjusted in accordance with renal function.

**allopurinol 100 mg tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2600W | | | | | | | |
| NP | 1 | 2 | 0.00 | 19.12 | 20.66 | [a] Allopurinol Sandoz [SZ] | [a] ALLOPURINOL-WGR [WG] |
| | | | | | | [a] Allosig [RF] | [a] APO-ALLOPURINOL [TX] |
| | | | | | | [a] Progout 100 [AF] | [a] Progout Viatris [AL] |
| | | | [B]5.41 | 24.53 | 20.66 | [a] Zyloprim [RW] | |

**allopurinol 300 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2604C | | | | | | | |
| NP | 1 | 2 | 0.00 | 18.10 | 19.64 | [a] Allopurinol Sandoz [SZ] | [a] ALLOPURINOL-WGR [WG] |
| | | | | | | [a] Allosig [RF] | [a] APO-ALLOPURINOL [TX] |
| | | | | | | [a] Progout 300 [AF] | [a] Progout Viatris [AL] |
| | | | [B]5.38 | 23.48 | 19.64 | [a] Zyloprim [RW] | |

## ALLOPURINOL

**Note** The dose should be adjusted in accordance with renal function.

**Restricted benefit**

***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**allopurinol 100 mg tablet, 200**

| 13358C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *23.88 | 25.00 | [a] Allopurinol Sandoz [SZ] | [a] ALLOPURINOL-WGR [WG] |
| | | | | | | [a] Allosig [RF] | [a] APO-ALLOPURINOL [TX] |
| | | | | | | [a] Progout 100 [AF] | [a] Progout Viatris [AL] |
| | | | [B]10.82 | 34.70 | 25.00 | [a] Zyloprim [RW] | |

**allopurinol 300 mg tablet, 60**

| 13575L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *21.84 | 23.38 | [a] Allopurinol Sandoz [SZ] | [a] ALLOPURINOL-WGR [WG] |
| | | | | | | [a] Allosig [RF] | [a] APO-ALLOPURINOL [TX] |
| | | | | | | [a] Progout 300 [AF] | [a] Progout Viatris [AL] |
| | | | [B]10.76 | 32.60 | 23.38 | [a] Zyloprim [RW] | |

## FEBUXOSTAT

**Authority Required (STREAMLINED)**
***8921***
Chronic gout
**Clinical criteria:**

- The condition must be either chronic gouty arthritis or chronic tophaceous gout, **AND**
- Patient must have a medical contraindication to allopurinol; **OR**
- Patient must have a documented history of allopurinol hypersensitivity syndrome; **OR**
- Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

**febuxostat 80 mg tablet, 28**

| 10445R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 51.08 | 25.00 | [a] Adenuric [FK] | [a] Febexic [CR] |

## FEBUXOSTAT

**Authority Required (STREAMLINED)**
***14313***
Chronic gout
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be either chronic gouty arthritis or chronic tophaceous gout, **AND**
- Patient must have a medical contraindication to allopurinol; **OR**
- Patient must have a documented history of allopurinol hypersensitivity syndrome; **OR**
- Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

**febuxostat 80 mg tablet, 28**

| 13519M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *87.80 | 25.00 | [a] Adenuric [FK] | [a] Febexic [CR] |

### *Preparations increasing uric acid excretion*

## PROBENECID

**probenecid 500 mg tablet, 100**

| 1940D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 74.85 | 25.00 | Pro-Cid [FF] |

## PROBENECID

**Restricted benefit**
***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**probenecid 500 mg tablet, 100**

| 13942T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *136.38 | 25.00 | Pro-Cid [FF] |

### *Preparations with no effect on uric acid metabolism*

## COLCHICINE

**colchicine 500 microgram tablet, 30**

| 3410L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.88 | 19.42 | [a] ARX-Colchicine [XT] | [a] COLCHICINE-WGR [WG] |
| | | | | | | [a] Colcine [CR] | [a] Lengout [LN] |
| | | | [B]2.02 | 19.90 | 19.42 | [a] Colgout [AS] | |

# DRUGS FOR TREATMENT OF BONE DISEASES

## DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

### *Bisphosphonates*

## ALENDRONATE

**Restricted benefit**

***6323***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

***6310***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

***6327***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**alendronate 70 mg tablet, 4**

| 8511Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.24 | 19.78 | [a] Alendronate Sandoz [SZ] | [a] ALENDRONATE-WGR [WG] |
| | | | | | | [a] APO-Alendronate [TX] | [a] Fonat [AL] |

## ALENDRONATE

**Restricted benefit**

***14309***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**

***14242***

Osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**

***14291***

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**alendronate 70 mg tablet, 4**

| 13499L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.12 | 23.66 | [a] Alendronate Sandoz [SZ] | [a] ALENDRONATE-WGR [WG] |
| | | | | | | [a] APO-Alendronate [TX] | [a] Fonat [AL] |

## IBANDRONATE

**Restricted benefit**

***16679***

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**ibandronate 50 mg tablet, 28**

| 9357L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 213.96 | 25.00 | Bondronat [IX] |

## PAMIDRONATE DISODIUM

**Restricted benefit**

***16577***

Symptomatic Paget disease of bone

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**pamidronate disodium 60 mg/10 mL injection, 10 mL vial**

| 8463K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 72.00 | 25.00 | Pamisol [PF] |

## RISEDRONATE

**Restricted benefit**

***16577***

Symptomatic Paget disease of bone

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**risedronate sodium 30 mg tablet, 28**

| 8482K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 176.40 | 25.00 | Actonel [TT] |

## RISEDRONATE

**Restricted benefit**

***6323***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

***6310***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

***6327***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**risedronate sodium 5 mg tablet, 28**

| 8481J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 37.65 | 25.00 | Actonel [TT] |

**risedronate sodium 35 mg tablet, 4**

| 8621R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 34.17 | 25.00 | [a] APO-Risedronate [TX] | [a] Risedronate Sandoz [SZ] |
| | | | | | | [a] RISEDRONATE-WGR [WG] | |

**risedronate sodium 35 mg enteric tablet, 4**

| 8972F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 34.17 | 25.00 | Actonel EC [TT] |

**risedronate sodium 150 mg tablet, 1**

| 9391G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 35.84 | 25.00 | [a] Actonel Once-a-Month [TT] | [a] APO-Risedronate [TX] |
| | | | | | | [a] Risedronate Way [IX] | |

## RISEDRONATE

**Restricted benefit**

***14234***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

***14235***

Osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**Restricted benefit**

***14263***

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**risedronate sodium 5 mg tablet, 28**

| 13360E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *60.94 | 25.00 | Actonel [TT] |

**risedronate sodium 35 mg enteric tablet, 4**

| 13364J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *53.98 | 25.00 | Actonel EC [TT] |

**risedronate sodium 35 mg tablet, 4**

| 13459J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *53.98 | 25.00 | [a] APO-Risedronate [TX] | [a] Risedronate Sandoz [SZ] |
| | | | | | | [a] RISEDRONATE-WGR [WG] | |

**risedronate sodium 150 mg tablet, 1**

| 13488X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *57.32 | 25.00 | [a] Actonel Once-a-Month [TT] | [a] APO-Risedronate [TX] |
| | | | | | | [a] Risedronate Way [IX] | |

## ZOLEDRONIC ACID

**Authority Required (STREAMLINED)**

***5710***

Symptomatic Paget disease of bone

Only 1 treatment each year per patient will be PBS-subsidised

**zoledronic acid 5 mg/100 mL injection, 100 mL vial**

| 9350D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 74.05 | 25.00 | [a] Aclasta [HX] | [a] Osteovan [SZ] |
| | | | | | | [a] Zoledasta [TX] | [a] Zoledronate-RDY 5 [RI] |

## ZOLEDRONIC ACID

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority Required (STREAMLINED)**

***6308***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority Required (STREAMLINED)**

***6313***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority Required (STREAMLINED)**

***6318***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**zoledronic acid 5 mg/100 mL injection, 100 mL vial**

| 9288W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 74.05 | 25.00 | [a] Aclasta [HX] | [a] Osteovan [SZ] |

| 9288W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Zoledasta [TX] | [a] Zoledronate-RDY 5 [RI] |

***Bisphosphonates, combinations***

## ALENDRONATE + COLECALCIFEROL

**Authority Required (STREAMLINED)**

***6307***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

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**Authority Required (STREAMLINED)**

***6320***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

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**Authority Required (STREAMLINED)**

***6315***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

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### alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4

| 9012H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.32 | 22.86 | Fosamax Plus [MQ] |

## ALENDRONATE + COLECALCIFEROL

**Authority Required (STREAMLINED)**

***6306***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority Required (STREAMLINED)**

***6325***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority Required (STREAMLINED)**

***6319***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

### alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

| 9183H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.32 | 22.86 | Fosamax Plus 70 mg/140 mcg [MQ] |

## ALENDRONATE + COLECALCIFEROL

**Authority Required (STREAMLINED)**

***15032***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority Required (STREAMLINED)**

***14898***

Osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority Required (STREAMLINED)**

***14993***

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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**alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4**

| 13835E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *28.28 | 25.00 | Fosamax Plus 70 mg/140 mcg [MQ] |

## ALENDRONATE + COLECALCIFEROL

**Authority Required (STREAMLINED)**

***15024***

Corticosteroid-induced osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

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**Authority Required (STREAMLINED)**

***15011***

Osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

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**Authority Required (STREAMLINED)**

***15035***

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

**alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4**

| 14003B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *28.28 | 25.00 | Fosamax Plus [MQ] |

## *Other drugs affecting bone structure and mineralization*

### CALCITRIOL

**Authority Required (STREAMLINED)**

***5401***

Hypocalcaemia

**Clinical criteria:**

- The condition must be due to renal disease.

**Authority Required (STREAMLINED)**

***5255***

Hypoparathyroidism

**Authority Required (STREAMLINED)**

***5089***

Hypophosphataemic rickets

**Authority Required (STREAMLINED)**

***5114***

Vitamin D-resistant rickets

**Authority Required (STREAMLINED)**

***5402***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

| 2502Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 3 | 0.00 | 29.99 | 25.00 | [a] Calciprox [ZS] | [a] CALITROL [XT] |
| | | | | | | [a] Sical [AF] | |
| | | | [B]2.23 | 32.22 | 25.00 | [a] Rocaltrol [IX] | |

### CALCITRIOL

**Authority Required (STREAMLINED)**

***14322***

Hypocalcaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be due to renal disease.

**Authority Required (STREAMLINED)**

***14287***

Hypoparathyroidism

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required (STREAMLINED)**

***14231***

Hypophosphataemic rickets

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required (STREAMLINED)**

***14296***

Vitamin D-resistant rickets

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required (STREAMLINED)**

***14259***

Established osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

### calcitriol 0.25 microgram capsule, 100

| 13457G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 3 | 0.00 | *45.62 | 25.00 | [a] Calciprox [ZS] | [a] CALITROL [XT] |
| | | | | | | [a] Sical [AF] | |
| | | | [B]4.46 | 50.08 | 25.00 | [a] Rocaltrol [IX] | |

## DENOSUMAB

**Note** Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

**Authority Required (STREAMLINED)**

***16514***

Giant cell tumour of bone

**Clinical criteria:**

- Patient must be one in whom surgical resection is not feasible; **OR**
- Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity.

**Population criteria:**

- Patient must be an adult; **OR**
- Patient must be a skeletally mature adolescent.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### denosumab 120 mg/mL injection, 1 mL syringe

| 15001M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 339.43 | 25.00 | Xgeva [XT] |

## DENOSUMAB

**Authority Required (STREAMLINED)**

***16608***

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***16512***

Bone metastases

**Clinical criteria:**

- The condition must be due to castration-resistant prostate cancer.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### denosumab 120 mg/mL injection, 1 mL syringe

| 15013E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 339.43 | 25.00 | Xgeva [XT] |

## DENOSUMAB

**Note** Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Authority Required (STREAMLINED)**

***16514***

Giant cell tumour of bone

**Clinical criteria:**

- Patient must be one in whom surgical resection is not feasible; **OR**
- Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity.

**Population criteria:**

- Patient must be an adult; **OR**
- Patient must be a skeletally mature adolescent.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### denosumab 120 mg/1.7 mL injection, 1.7 mL vial

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10061M | | | | | | | |
| NP | 1 | 5 | 0.00 | 290.70 | 25.00 | [a] GANVADO [XW] | [a] Osenvelt [EW] |
| | | | | | | [a] Wyost [SZ] | [a] Xgeva [XT] |

## DENOSUMAB

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Authority Required (STREAMLINED)**

***16608***

Bone metastases

**Clinical criteria:**

- The condition must be due to breast cancer.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***16512***

Bone metastases

**Clinical criteria:**

- The condition must be due to castration-resistant prostate cancer.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### denosumab 120 mg/1.7 mL injection, 1.7 mL vial

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5110Y | | | | | | | |
| NP | 1 | 5 | 0.00 | 290.70 | 25.00 | [a] GANVADO [XW] | [a] Osenvelt [EW] |
| | | | | | | [a] Wyost [SZ] | [a] Xgeva [XT] |

## DENOSUMAB

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Authority Required (STREAMLINED)**

***6548***

Osteoporosis

**Population criteria:**

- Patient must be aged 70 years or older.

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority Required (STREAMLINED)**

***6524***

Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

### denosumab 60 mg/mL injection, 1 mL syringe

| 5457F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 160.37 | 25.00 | [a] CORORA [XW] | [a] Jubbonti [SZ] |
| | | | | | | [a] Prolia [XT] | [a] Stoboclo [EW] |

## RALOXIFENE

**Authority Required (STREAMLINED)**

***6314***

Established post-menopausal osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

### raloxifene hydrochloride 60 mg tablet, 28

| 8363E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 30.69 | 25.00 | [a] Fixta 60 [ZS] | [a] RALOVISTA [RF] |
| | | | | | | [a] Raloxifene GH [GQ] | |
| | | | [B]3.98 | 34.67 | 25.00 | [a] Evista [BZ] | |

## RALOXIFENE

**Authority Required (STREAMLINED)**

***14274***

Established post-menopausal osteoporosis

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**raloxifene hydrochloride 60 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13426P NP | 2 | 5 | 0.00 | *47.02 | 25.00 | [a] Fixta 60 [ZS] | [a] RALOVISTA [RF] |
| | | | | | | [a] Raloxifene GH [GQ] | |
| | | | [B]7.96 | 54.98 | 25.00 | [a] Evista [BZ] | |

## ROMOSOZUMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18927***

Severe established osteoporosis

Treatment Phase: Initial treatment - Second-line therapy

**Clinical criteria:**

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy, **AND**
- Patient must not have received PBS-subsidised treatment with any of: (i) teriparatide, (ii) abaloparatide, or (iii) romosozumab; **OR**
- Patient must have developed intolerance to: (i) teriparatide, or (ii) abaloparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

**Treatment criteria:**

- Must be treated by a consultant physician.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

**Authority Required**

***16023***

Severe established osteoporosis

Treatment Phase: Continuing treatment - Second-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy, **AND**
- The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.

**romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12301K | 1 | 5 | 0.00 | 395.12 | 25.00 | Evenity [AN] |

## ROMOSOZUMAB

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**

***18972***

Severe established osteoporosis

Treatment Phase: Initial treatment - First-line therapy

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with any of: (i) anti-resorptive therapy, (ii) teriparatide, (iii) romosozumab, (iv) abaloparatide; **OR**
- Patient must have developed intolerance to abaloparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy, **AND**
- Patient must be at very high risk of fracture, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must have had a symptomatic fracture due to minimal trauma, **AND**
- Patient must have had at least 1 hip or symptomatic vertebral fracture in the previous 24 months; **OR**
- Patient must have had at least 2 fractures including 1 symptomatic new fracture in the previous 24 months, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy.

**Treatment criteria:**

- Must be treated by a consultant physician.

Details of fracture history including the date(s), site(s), the symptoms associated with the fracture(s) and the score of the qualifying BMD measurement must be provided at the time of application.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Anti-resorptive therapies for osteoporosis include alendronate sodium, risedronate sodium, raloxifene hydrochloride, denosumab and zoledronic acid.

**Authority Required**

***16022***

Severe established osteoporosis

Treatment Phase: Continuing treatment - First-line therapy

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition as first-line therapy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy.

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.

### romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14641N | 1 | 5 | 0.00 | 395.12 | 25.00 | Evenity [AN] |

## TERIPARATIDE

**Note** Pharmaceutical benefits that have the form teriparatide 250 microgram/mL injection, 2.4 mL cartridge and the pharmaceutical benefits that have the form teriparatide 250 microgram/mL injection, 2.4 mL pen device are equivalent for the purposes of substitution.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15536***

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Treatment criteria:**

- Must be treated by a specialist; **OR**
- Must be treated by a consultant physician.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

**teriparatide 250 microgram/mL injection, 2.4 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14482F | 2 | 2 | 0.00 | *336.92 | 25.00 | [a] Teriparatide Lupin [GQ] | [a] Terrosa [FX] |

**teriparatide 250 microgram/mL injection, 2.4 mL cartridge**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15188J | 2 | 2 | 0.00 | *336.92 | 25.00 | [a] Ritosa [XT] |

## TERIPARATIDE

**Note** Pharmaceutical benefits that have the form teriparatide 250 microgram/mL injection, 2.4 mL cartridge and the pharmaceutical benefits that have the form teriparatide 250 microgram/mL injection, 2.4 mL pen device are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***19012***

Severe established osteoporosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist; **OR**
- Must be treated by a consultant physician.

**Clinical criteria:**

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy, **AND**
- Patient must not have received PBS-subsidised treatment with any of: (i) romosozumab, (ii) abaloparatide; **OR**
- Patient must have developed intolerance to: (i) romosozumab, or (ii) abaloparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be documented in the patient's medical record.

**Authority Required (STREAMLINED)**

***12270***

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

**Treatment criteria:**

- Must be treated by a specialist; **OR**
- Must be treated by a consultant physician.

**Note** Up to a maximum of 18 pens will be reimbursed through the PBS.

**teriparatide 250 microgram/mL injection, 2.4 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14093R | 1 | 5 | 0.00 | 173.14 | 25.00 | [a] Teriparatide Lupin [GQ] | [a] Terrosa [FX] |

**teriparatide 250 microgram/mL injection, 2.4 mL cartridge**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15152L | 1 | 5 | 0.00 | 173.14 | 25.00 | [a] Ritosa [XT] |

## VOSORITIDE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***13977***

Achondroplasia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a diagnosis of achondroplasia, confirmed by appropriate genetic testing, **AND**
- Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months.

**Treatment criteria:**

- Must be treated by a medical specialist, experienced in the management of achondroplasia; **OR**
- Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Appropriate genetic testing constitutes testing for FGFR3 gene mutation.

In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records.

Additional radiographic evidence is not required until patient has begun puberty.

In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.

**Authority Required**

***13998***

Achondroplasia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS subsidised vosoritide treatment for this condition, **AND**
- Patient must not have evidence of growth plate closure demonstrated by at least one of the following: i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months.

**Treatment criteria:**

- Must be treated by a medical specialist, experienced in the management of achondroplasia; **OR**
- Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records.

Additional radiographic evidence is not required until patient has begun puberty.

In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.

**vosoritide 400 microgram injection [10 vials] (&) inert substance diluent [10 x 0.5 mL syringes], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13275Q | 3 | 5 | 0.00 | *28,409.91 | 25.00 | Voxzogo [IO] |

**vosoritide 560 microgram injection [10 vials] (&) inert substance diluent [10 x 0.7 mL syringes], 1 pack**

| 13274P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | 0.00 | *28,409.91 | 25.00 | Voxzogo [IO] |

**vosoritide 1.2 mg injection [10 vials] (&) inert substance diluent [10 x 0.6 mL syringes], 1 pack**

| 13270K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 3 | 5 | 0.00 | *28,409.91 | 25.00 | Voxzogo [IO] |

# OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

## OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

### *Other drugs for disorders of the musculo-skeletal system*

## PALOVAROTENE

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17017***

Fibrodysplasia ossificans progressiva (FOP)

Treatment Phase: Chronic treatment

**Clinical criteria:**

- Patient must have a diagnosis of FOP, confirmed by genetic testing.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of FOP; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of FOP.

**Population criteria:**

- Patient must be a female aged 8 years or older; **OR**
- Patient must be a male aged 10 years or older.

At the time of the authority application, the medical practitioner must request the appropriate combination of packs to provide treatment at the recommended dose for chronic treatment, based on the age and weight of the patient, adequate for 4 weeks according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Appropriate genetic testing constitutes testing for a pathogenic variant of the Activin A receptor type I (ACVR1) gene. Confirm that evidence of the presence of a pathogenic mutation of the ACVR1 gene is documented/retained in the patient's medical records once only with the first PBS prescription.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**palovarotene 1 mg capsule, 28**

| 15023Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 10,322.57 | 25.00 | Sohonos [IS] |

**palovarotene 1.5 mg capsule, 28**

| 14968T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 15,317.96 | 25.00 | Sohonos [IS] |

**palovarotene 2.5 mg capsule, 28**

| 14980K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 25,308.36 | 25.00 | Sohonos [IS] |

**palovarotene 5 mg capsule, 28**

| 14966Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 50,284.36 | 25.00 | Sohonos [IS] |

## PALOVAROTENE

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17018***

Fibrodysplasia ossificans progressiva (FOP)

Treatment Phase: Flare-up (acute) treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be experiencing a FOP flare-up; **OR**
- Patient must be at high risk of a FOP flare-up.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of FOP; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of FOP.

**Population criteria:**

- Patient must be a female aged 8 years or older; **OR**
- Patient must be a male aged 10 years or older.

Flare-up treatment should begin at the onset of the first symptom indicative of a FOP flare-up or substantial high-risk traumatic event likely to lead to a flare-up. Symptoms of a FOP flareup typically include but are not limited to localised pain, soft tissue swelling/inflammation, redness, warmth, decreased joint range of motion, and stiffness. Examples of a high risk substantial traumatic event include surgery, intramuscular immunisation, mandibular blocks for dental work, muscle fatigue, blunt muscle trauma from bumps, bruises, falls, or influenza-like viral illnesses.

At the time of the authority application, the medical practitioner must request the appropriate combination of packs to provide treatment at the recommended dose for flare-up treatment based on the age and weight of the patient, adequate for 12 weeks of treatment or in the presence of persistent flare-up symptoms to extend treatment in 4-week intervals according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested.

If the patient experiences another flare-up (i.e., new flare-up location or marked worsening of the original flare-up) at any time during flare-up treatment, the flare-up 12-week treatment should be restarted.

**palovarotene 1 mg capsule, 28**

| 14967R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 10,322.57 | 25.00 | Sohonos [IS] |

**palovarotene 1.5 mg capsule, 28**

| 14989X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 15,317.96 | 25.00 | Sohonos [IS] |

**palovarotene 2.5 mg capsule, 28**

| 14982M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 25,308.36 | 25.00 | Sohonos [IS] |

**palovarotene 5 mg capsule, 28**

| 14981L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 50,284.36 | 25.00 | Sohonos [IS] |

**palovarotene 10 mg capsule, 28**

| 15087C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 2 | 0.00 | *200,363.36 | 25.00 | Sohonos [IS] |

# NERVOUS SYSTEM

## ANALGESICS

### OPIOIDS

#### *Natural opium alkaloids*

## CODEINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

***10768***

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**codeine phosphate hemihydrate 30 mg tablet, 20**

| 5063L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 24.29 | 25.00 | Aspen Pharmacare Australia Pty Ltd [AS] |

## CODEINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

***10766***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**codeine phosphate hemihydrate 30 mg tablet, 20**

| 12054K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 0.5 | 0 | 0.00 | *24.23 | 25.00 | Aspen Pharmacare Australia Pty Ltd [AS] |

## CODEINE

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***10766***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**codeine phosphate hemihydrate 30 mg tablet, 20**

| 12065B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 0.5 | 0 | 0.00 | *24.23 | 25.00 | Aspen Pharmacare Australia Pty Ltd [AS] |

## CODEINE

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Restricted benefit**

***10771***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10772***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10764***

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**codeine phosphate hemihydrate 30 mg tablet, 20**

| 1214X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 24.29 | 25.00 | Aspen Pharmacare Australia Pty Ltd [AS] |

## HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

***10859***

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**hydromorphone hydrochloride 2 mg tablet, 20**

| 5115F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 26.48 | 25.00 | Dilaudid [MF] |

**hydromorphone hydrochloride 4 mg tablet, 20**

| 5116G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 28.68 | 25.00 | Dilaudid [MF] |

**hydromorphone hydrochloride 8 mg tablet, 20**

| 5117H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 36.84 | 25.00 | Dilaudid [MF] |

## HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

***10758***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**hydromorphone hydrochloride 2 mg tablet, 20**

| 12045Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 0.5 | 0 | 0.00 | *25.59 | 25.00 | Dilaudid [MF] |

**hydromorphone hydrochloride 4 mg tablet, 20**

| 12032G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 0.5 | 0 | 0.00 | *26.95 | 25.00 | Dilaudid [MF] |

**hydromorphone hydrochloride 8 mg tablet, 20**

| 12010D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 0.5 | 0 | 0.00 | *32.01 | 25.00 | Dilaudid [MF] |

## HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***10758***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**hydromorphone hydrochloride 2 mg tablet, 20**

| 12047C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 0.5 | 0 | 0.00 | *25.59 | 25.00 | Dilaudid [MF] |

**hydromorphone hydrochloride 4 mg tablet, 20**

| 12046B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 0.5 | 0 | 0.00 | *26.95 | 25.00 | Dilaudid [MF] |

**hydromorphone hydrochloride 8 mg tablet, 20**

| 12016K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 0.5 | 0 | 0.00 | *32.01 | 25.00 | Dilaudid [MF] |

## HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Note** Pharmaceutical benefits that have the brand Hydromorphone hydrochloride oral solution, USP (Medsurge) and pharmaceutical benefits that have the brand Hikma are equivalent for the purposes of substitution in the case of a shortage.

**Restricted benefit**

***10859***

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

### hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL

| 12559B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 422.96 | 25.00 | [a] Hikma [LM] |

### hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL

| 13799G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 517.98 | 25.00 | [a] Hydromorphone hydrochloride oral solution, USP (Medsurge) [DZ] |

## HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Restricted benefit**

***10777***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10770***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10764***

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### hydromorphone hydrochloride 2 mg tablet, 20

| 8541M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 26.48 | 25.00 | Dilaudid [MF] |

### hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules

| 8420E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 24.88 | 25.00 | [a] Dilaudid [MF] | [a] Hydromorphone-hameln [HW] |
| | | | | | | [a] HYDROMORPHONE JUNO [JU] | [a] MEDSURGE HYDROMORPHONE 2 mg/1 mL [DZ] |

### hydromorphone hydrochloride 4 mg tablet, 20

| 8542N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 28.68 | 25.00 | Dilaudid [MF] |

### hydromorphone hydrochloride 8 mg tablet, 20

| 8543P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 36.84 | 25.00 | Dilaudid [MF] |

### hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

| 8421F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 26.41 | 25.00 | [a] Dilaudid-HP [MF] | [a] Hydromorphone-hameln-HP [HW] |
| | | | | | | [a] HYDROMORPHONE JUNO-HP [JU] | [a] MEDSURGE HYDROMORPHONE HP 10 mg/1 mL [DZ] |

## HYDROMORPHONE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Note** Pharmaceutical benefits that have the brand Hydromorphone hydrochloride oral solution, USP (Medsurge) and pharmaceutical benefits that have the brand Hikma are equivalent for the purposes of substitution in the case of a shortage.

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**Restricted benefit**

***10777***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10770***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10764***

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

| 12582F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 422.96 | 25.00 | [a] Hikma [LM] |

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

| 13796D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 517.98 | 25.00 | [a] Hydromorphone hydrochloride oral solution, USP (Medsurge) [DZ] |

## MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

***10859***

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL**

| 5237P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 61.81 | 25.00 | [a] Morphine Phebra [FF] | [a] Ordine 2 [XT] |

**morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL**

| 5238Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 103.53 | 25.00 | [a] Morphine Phebra [FF] | [a] Ordine 5 [XT] |

**morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL**

| 5239R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 151.99 | 25.00 | Ordine 10 [XT] |

**morphine sulfate pentahydrate 30 mg tablet, 20**

| 5163R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 31.32 | 25.00 | Anamorph [RW] |

## MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

***10839***

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; **OR**
- The treatment must be part of pre-operative care; **OR**

- The treatment must be used as an analgesic adjunct in general anaesthesia.

**morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules**

| 5169C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 27.58 | 25.00 | MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ] |

**morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules**

| 10858L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 26.23 | 25.00 | Morphine Juno [JU] |

**morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules**

| 5170D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 29.61 | 25.00 | MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ] |

## MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

***10758***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**morphine sulfate pentahydrate 30 mg tablet, 20**

| 12067D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 0.5 | 0 | 0.00 | *28.59 | 25.00 | Anamorph [RW] |

## MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

**Restricted benefit**

***10839***

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; **OR**
- The treatment must be part of pre-operative care; **OR**
- The treatment must be used as an analgesic adjunct in general anaesthesia.

**morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules**

| 5168B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 24.94 | 25.00 | [a] MORPHINE SULFATE 10 mg/1 mL MEDSURGE [DZ] |

**morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules**

| 10863R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 24.18 | 25.00 | [a] Morphine Juno [JU] |

## MORPHINE

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***10758***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**

- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**morphine sulfate pentahydrate 30 mg tablet, 20**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12009C NP | 0.5 | 0 | 0.00 | *28.59 | 25.00 | Anamorph [RW] |

## MORPHINE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***10836***

Chronic severe disabling pain

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

**morphine sulfate pentahydrate 200 mg modified release tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8453X NP | 1 | 0 | 0.00 | 119.50 | 25.00 | MS Contin [MF] |

## MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Restricted benefit**

***10765***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; **OR**
- The treatment must be part of pre-operative care; **OR**
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10762***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**

- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; **OR**
- The treatment must be part of pre-operative care; **OR**
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10764***

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules**

| 1645N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 27.58 | 25.00 | MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ] |

**morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules**

| 10874H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 26.23 | 25.00 | Morphine Juno [JU] |

**morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules**

| 1647Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 29.61 | 25.00 | MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ] |

**morphine hydrochloride trihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules**

| 10869C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 31.86 | 25.00 | Morphine Juno [JU] |

### morphine hydrochloride trihydrate 100 mg/5 mL injection, 5 x 5 mL ampoules

| 10878M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 37.73 | 25.00 | Morphine Juno [JU] |

## MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Restricted benefit**

***10777***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10770***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10764***

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL**

| 2122Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 61.81 | 25.00 | [a] Morphine Phebra [FF] | [a] Ordine 2 [XT] |

**morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL**

| 2123R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 103.53 | 25.00 | [a] Morphine Phebra [FF] | [a] Ordine 5 [XT] |

**morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL**

| 2124T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 151.99 | 25.00 | Ordine 10 [XT] |

**morphine sulfate pentahydrate 30 mg tablet, 20**

| 1646P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 31.32 | 25.00 | Anamorph [RW] |

## MORPHINE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority Required (STREAMLINED)**

***10755***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***10748***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***10752***

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine sulfate pentahydrate 5 mg modified release tablet, 28**

| 8035X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 26.66 | 25.00 | MS Contin [MF] |

**morphine sulfate pentahydrate 10 mg modified release tablet, 28**

| 1653B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 27.02 | 25.00 | MS Contin [MF] |

**morphine sulfate pentahydrate 10 mg modified release capsule, 28**

| 8349K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 29.29 | 25.00 | Kapanol [YN] |

**morphine sulfate pentahydrate 15 mg modified release tablet, 28**

| 8489T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 32.83 | 25.00 | MS Contin [MF] |

**morphine sulfate pentahydrate 20 mg modified release capsule, 28**

| 2839K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 30.15 | 25.00 | Kapanol [YN] |

**morphine sulfate pentahydrate 30 mg modified release tablet, 28**

| 1654C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 37.06 | 25.00 | MS Contin [MF] |

**morphine sulfate pentahydrate 30 mg modified release capsule, 14**

| 8491X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 29.65 | 25.00 | MS Mono [MF] |

**morphine sulfate pentahydrate 50 mg modified release capsule, 28**

| 2840L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 41.76 | 25.00 | Kapanol [YN] |

**morphine sulfate pentahydrate 60 mg modified release tablet, 28**

| 1655D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 49.88 | 25.00 | MS Contin [MF] |

**morphine sulfate pentahydrate 60 mg modified release capsule, 14**

| 8492Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 37.04 | 25.00 | MS Mono [MF] |

**morphine sulfate pentahydrate 90 mg modified release capsule, 14**

| 8493B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 40.57 | 25.00 | MS Mono [MF] |

**morphine sulfate pentahydrate 100 mg modified release tablet, 28**

| 1656E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 62.11 | 25.00 | MS Contin [MF] |

**morphine sulfate pentahydrate 100 mg modified release capsule, 28**

| 2841M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 60.76 | 25.00 | Kapanol [YN] |

**morphine sulfate pentahydrate 120 mg modified release capsule, 14**

| 8494C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 49.87 | 25.00 | MS Mono [MF] |

## MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Restricted benefit**

***10891***

Cancer pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have cancer pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10775***

Cancer pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have cancer pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10837***

Cancer pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine sulfate pentahydrate 10 mg tablet, 20**

| 8669G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 24.44 | 25.00 | Sevredol [MF] |

**morphine sulfate pentahydrate 20 mg tablet, 20**

| 8670H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 25.19 | 25.00 | Sevredol [MF] |

**morphine sulfate pentahydrate 30 mg tablet, 20**

| 14654G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 31.32 | 25.00 | Anamorph [RW] |

## MORPHINE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

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Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

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**Authority Required**

***10756***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required**

***10858***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required**

***10814***

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**morphine sulfate pentahydrate 200 mg modified release tablet, 28**

12055L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 119.50 | 25.00 | MS Contin [MF] |

NP

## MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Restricted benefit**

***10765***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; **OR**
- The treatment must be part of pre-operative care; **OR**
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10762***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; **OR**
- The treatment must be part of pre-operative care; **OR**
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10764***

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules

| 1644M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 24.94 | 25.00 | [a] | MORPHINE SULFATE 10 mg/1 mL MEDSURGE [DZ] |

### morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules

| 10864T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 24.18 | 25.00 | [a] | Morphine Juno [JU] |

## OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

***10768***

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

### oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL

| 5190E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 32.93 | 25.00 | OxyNorm Liquid 1mg/mL [MF] |

**oxycodone hydrochloride 5 mg capsule, 20**

| 5191F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 31.56 | 25.00 | [a] Oxycodone BNM [BZ] | [a] OxyNorm [MF] |

**oxycodone hydrochloride 5 mg tablet, 20**

| 5195K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 22.83 | 24.37 | [a] Mayne Pharma Oxycodone IR [SZ] | [a] Oxycodone Viatris [MQ] |
| | | | | | | [a] Oxyndone [TX] | |
| | | | [B]2.00 | 24.83 | 24.37 | [a] ENDONE [AF] | |

**oxycodone hydrochloride 10 mg capsule, 20**

| 5197M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 26.35 | 25.00 | [a] Oxycodone BNM [BZ] | [a] OxyNorm [MF] |

## OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

***10766***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 10 mg capsule, 20**

| 12074L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 0.5 | 0 | 0.00 | *25.51 | 25.00 | [a] Oxycodone BNM [BZ] | [a] OxyNorm [MF] |

## OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***10766***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 10 mg capsule, 20**

| 12031F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 0.5 | 0 | 0.00 | *25.51 | 25.00 | [a] Oxycodone BNM [BZ] | [a] OxyNorm [MF] |

## OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Note** Pharmaceutical benefits that have the forms Oxycodone hydrochloride 5 mg capsule, 20 and oxycodone hydrochloride 5 mg capsule, 10 are equivalent for the purposes of substitution.

**Restricted benefit**

***10766***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 5 mg capsule, 10**

| 12311Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 25.83 | 25.00 | [a] OxyNorm [MF] |

**oxycodone hydrochloride 5 mg capsule, 20**

| 15423R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 0.5 | 0 | 0.00 | *28.74 | 25.00 | [a] Oxycodone BNM [BZ] | [a] OxyNorm [MF] |

## OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Note** Pharmaceutical benefits that have the forms Oxycodone hydrochloride 5 mg tablet, 20 and oxycodone hydrochloride 5 mg tablet, 10 are equivalent for the purposes of substitution.

**Restricted benefit**

***10766***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 5 mg tablet, 10**

| 13234M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 21.58 | 23.12 | [a] Oxycodone Viatris [MQ] | |
| | | | [B]1.00 | 22.58 | 23.12 | [a] ENDONE [AF] | |

**oxycodone hydrochloride 5 mg tablet, 20**

| 15450E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 0.5 | 0 | 0.00 | *23.33 | 24.87 | [a] Mayne Pharma Oxycodone IR [SZ] | [a] Oxycodone Viatris [MQ] |
| | | | | | | [a] Oxyndone [TX] | |
| | | | [B]1.24 | 24.57 | 24.87 | [a] ENDONE [AF] | |

## OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the forms Oxycodone hydrochloride 5 mg capsule, 20 and oxycodone hydrochloride 5 mg capsule, 10 are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***16276***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is sharing the post-operative care of the patient with a medical practitioner.

**oxycodone hydrochloride 5 mg capsule, 10**

| 12314D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 25.83 | 25.00 | [a] OxyNorm [MF] |

**oxycodone hydrochloride 5 mg capsule, 20**

| 15495M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 0.5 | 0 | 0.00 | *28.74 | 25.00 | [a] Oxycodone BNM [BZ] | [a] OxyNorm [MF] |

## OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Pharmaceutical benefits that have the forms Oxycodone hydrochloride 5 mg tablet, 20 and oxycodone hydrochloride 5 mg tablet, 10 are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***16276***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is sharing the post-operative care of the patient with a medical practitioner.

**oxycodone hydrochloride 5 mg tablet, 10**

| 13233L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 21.58 | 23.12 | [a] Oxycodone Viatris [MQ] | |
| | | | [B]1.00 | 22.58 | 23.12 | [a] ENDONE [AF] | |

**oxycodone hydrochloride 5 mg tablet, 20**

| 15424T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 0.5 | 0 | 0.00 | *23.33 | 24.87 | [a] Mayne Pharma Oxycodone IR [SZ] | [a] Oxycodone Viatris [MQ] |
| | | | | | | [a] Oxyndone [TX] | |
| | | | [B]1.24 | 24.57 | 24.87 | [a] ENDONE [AF] | |

## OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Restricted benefit**

***10771***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10772***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through

consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10764***

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL**

| 8644Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 32.93 | 25.00 | OxyNorm Liquid 1mg/mL [MF] |

**oxycodone hydrochloride 5 mg tablet, 20**

| 2622B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 22.83 | 24.37 | [a] Mayne Pharma Oxycodone IR [SZ] | [a] Oxycodone Viatris [MQ] |
| | | | | | | [a] Oxyndone [TX] | |
| | | | [B]2.00 | 24.83 | 24.37 | [a] ENDONE [AF] | |

**oxycodone hydrochloride 5 mg capsule, 20**

| 8464L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 31.56 | 25.00 | [a] Oxycodone BNM [BZ] | [a] OxyNorm [MF] |

**oxycodone hydrochloride 10 mg capsule, 20**

| 8501K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 26.35 | 25.00 | [a] Oxycodone BNM [BZ] | [a] OxyNorm [MF] |

**oxycodone hydrochloride 20 mg capsule, 20**

| 8502L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 31.56 | 25.00 | [a] Oxycodone BNM [BZ] | [a] OxyNorm [MF] |

## OXYCODONE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority Required (STREAMLINED)**

***10755***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***10748***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***10752***

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**oxycodone hydrochloride 10 mg modified release tablet, 28**

| 8385H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 30.76 | 25.00 | [a] Oxycodone Sandoz [SZ] | [a] OxyContin [MF] |

**oxycodone hydrochloride 15 mg modified release tablet, 28**

| 9399Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 38.75 | 25.00 | OxyContin [MF] |

**oxycodone hydrochloride 20 mg modified release tablet, 28**

| 8386J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 38.99 | 25.00 | [a] Oxycodone Sandoz [SZ] | [a] OxyContin [MF] |

**oxycodone hydrochloride 30 mg modified release tablet, 28**

| 9400R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 51.92 | 25.00 | OxyContin [MF] |

**oxycodone hydrochloride 40 mg modified release tablet, 28**

| 8387K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 48.67 | 25.00 | [a] Oxycodone Sandoz [SZ] | [a] OxyContin [MF] |

**oxycodone hydrochloride 80 mg modified release tablet, 28**

| 8388L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 66.91 | 25.00 | [a] Oxycodone Sandoz [SZ] | [a] OxyContin [MF] |

## OXYCODONE + NALOXONE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority Required (STREAMLINED)**

***10755***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***10748***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***10752***

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg modified release tablet, 28**

| 10776E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 29.65 | 25.00 | [a] ARX-Oxycodone/Naloxone 2.5/1.25 [TX] | [a] Targin 2.5/1.25 mg [MF] |

**oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg modified release tablet, 28**

| 8000C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 32.90 | 25.00 | [a] ARX-Oxycodone/Naloxone 5/2.5 [TX]<br>[a] Targin 5/2.5mg [MF] | [a] OXYCODONE NALOXONE ADVZ XR 5/2.5 [BZ] |

**oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg modified release tablet, 28**

| 8934F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 33.72 | 25.00 | [a] ARX-Oxycodone/Naloxone 10/5 [TX]<br>[a] Targin 10/5mg [MF] | [a] OXYCODONE NALOXONE ADVZ XR 10/5 [BZ] |

**oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg modified release tablet, 28**

| 10757E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 42.48 | 25.00 | [a] ARX-Oxycodone/Naloxone 15/7.5 [TX] | [a] Targin 15/7.5mg [MF] |

**oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg modified release tablet, 28**

| 8935G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 44.27 | 25.00 | [a] ARX-Oxycodone/Naloxone 20/10 [TX]<br>[a] Targin 20/10mg [MF] | [a] OXYCODONE NALOXONE ADVZ XR 20/10 [BZ] |

**oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg modified release tablet, 28**

| 10758F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 58.28 | 25.00 | [a] ARX-Oxycodone/Naloxone 30/15 [TX]<br>[a] Targin 30/15 mg [MF] | [a] OXYCODONE NALOXONE ADVZ XR 30/15 [BZ] |

**oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg modified release tablet, 28**

| 8936H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 56.63 | 25.00 | [a] ARX-Oxycodone/Naloxone 40/20 [TX]<br>[a] Targin 40/20mg [MF] | [a] OXYCODONE NALOXONE ADVZ XR 40/20 [BZ] |

**oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28**

| 11102H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 83.74 | 25.00 | [a] ARX-Oxycodone/Naloxone 60/30 [TX] | [a] Targin 60/30 [MF] |

**oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28**

| 11111T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 87.13 | 25.00 | [a] ARX-Oxycodone/Naloxone 80/40 [TX] | [a] Targin 80/40 [MF] |

### *Phenylpiperidine derivatives*

## FENTANYL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority Required (STREAMLINED)**

***15996***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***15994***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***16000***

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**fentanyl 12 microgram/hour patch, 5**

| 8878G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 27.04 | 25.00 | [a] APO-Fentanyl [TX] | [a] Fentanyl Sandoz [SZ] |

**fentanyl 25 microgram/hour patch, 5**

| 8891Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 28.93 | 25.00 | [a] APO-Fentanyl [TX] | [a] Fentanyl Sandoz [SZ] |

**fentanyl 50 microgram/hour patch, 5**

| 8892B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 36.33 | 25.00 | [a] APO-Fentanyl [TX] | [a] Fentanyl Sandoz [SZ] |

**fentanyl 75 microgram/hour patch, 5**

| 8893C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 42.34 | 25.00 | [a] APO-Fentanyl [TX] | [a] Fentanyl Sandoz [SZ] |

**fentanyl 100 microgram/hour patch, 5**

| 8894D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 47.70 | 25.00 | [a] APO-Fentanyl [TX] | [a] Fentanyl Sandoz [SZ] |

### *Diphenylpropylamine derivatives*

## METHADONE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** This treatment is not recommended for use in ambulant patients.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority Required (STREAMLINED)**

***15996***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***15994***

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**

- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***16000***

Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**methadone hydrochloride 5 mg tablet, 20**

| 15377H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 23.39 | 24.93 | METHADONE-AFT [AE] |

**methadone hydrochloride 10 mg tablet, 20**

| 1609Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 25.26 | 25.00 | [a] METHADONE-AFT [AE] | [a] Physeptone [AS] |

**methadone hydrochloride 10 mg/mL injection, 5 x 1 mL vials**

| 14202L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 54.70 | 25.00 | Physeptone [AS] |

### *Oripavine derivatives*

## BUPRENORPHINE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority Required (STREAMLINED)**

***10755***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***10748***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***10752***

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**buprenorphine 5 microgram/hour patch, 2**

| 8865N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 27.40 | 25.00 | [a] B-Patch [IU] | [a] Bupredermal [TX] |
| | | | | | | [a] Buprenorphine Sandoz [SZ] | [a] Norspan [MF] |

**buprenorphine 10 microgram/hour patch, 2**

| 8866P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 33.25 | 25.00 | [a] B-Patch [IU] | [a] Bupredermal [TX] |
| | | | | | | [a] Buprenorphine Sandoz [SZ] | [a] Norspan [MF] |

**buprenorphine 15 microgram/hour patch, 2**

| 10770W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 36.82 | 25.00 | [a] B-Patch [IU] | [a] Bupredermal [TX] |
| | | | | | | [a] Buprenorphine Sandoz [SZ] | [a] Norspan [MF] |

**buprenorphine 20 microgram/hour patch, 2**

| 8867Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 40.40 | 25.00 | [a] B-Patch [IU] | [a] Bupredermal [TX] |
| | | | | | | [a] Buprenorphine Sandoz [SZ] | [a] Norspan [MF] |

**buprenorphine 25 microgram/hour patch, 2**

| 10756D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 43.78 | 25.00 | [a] Bupredermal [TX] | [a] Buprenorphine Sandoz [SZ] |
| | | | | | | [a] Norspan [MF] | |

**buprenorphine 30 microgram/hour patch, 2**

| 10755C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 47.16 | 25.00 | [a] Bupredermal [TX] | [a] Buprenorphine Sandoz [SZ] |
| | | | | | | [a] Norspan [MF] | |

**buprenorphine 40 microgram/hour patch, 2**

| 10746N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 53.94 | 25.00 | [a] Bupredermal [TX] | [a] Buprenorphine Sandoz [SZ] |
| | | | | | | [a] Norspan [MF] | |

## *Opioids in combination with non-opioid analgesics*

### PARACETAMOL + CODEINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

***10768***

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20**

| 3316M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO- Paracetamol/Codeine 500/30 [TX] | [a] APX-Paracetamol/Codeine [TY] |
| | | | | | | [a] Codalgin Forte [AF] | [a] Codapane Forte 500/30 [AL] |
| | | | | | | [a] Comfarol Forte [SZ] | [a] Paracetamol/Codeine GH 500/30 [GQ] |

| 3316M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Prodeine Forte [AV] | |
| | | | [B]3.81 | 20.91 | 18.64 | [a] Panadeine Forte [SW] | |

## PARACETAMOL + CODEINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

***10766***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

### paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

| 12066C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 0.5 | 0 | 0.00 | *17.60 | 19.14 | [a] APO- Paracetamol/Codeine 500/30 [TX] | [a] APX-Paracetamol/Codeine [TY] |
| | | | | | | [a] Codalgin Forte [AF] | [a] Codapane Forte 500/30 [AL] |
| | | | | | | [a] Comfarol Forte [SZ] | [a] Paracetamol/Codeine GH 500/30 [GQ] |
| | | | | | | [a] Prodeine Forte [AV] | |
| | | | [B]2.36 | 19.96 | 19.14 | [a] Panadeine Forte [SW] | |

## PARACETAMOL + CODEINE

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***10766***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

### paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

| 12022R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 0.5 | 0 | 0.00 | *17.60 | 19.14 | [a] APO- Paracetamol/Codeine 500/30 [TX] | [a] APX-Paracetamol/Codeine [TY] |
| | | | | | | [a] Codalgin Forte [AF] | [a] Codapane Forte 500/30 [AL] |
| | | | | | | [a] Comfarol Forte [SZ] | [a] Paracetamol/Codeine GH 500/30 [GQ] |
| | | | | | | [a] Prodeine Forte [AV] | |
| | | | [B]2.36 | 19.96 | 19.14 | [a] Panadeine Forte [SW] | |

## PARACETAMOL + CODEINE

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Restricted benefit**

***10771***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10772***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10764***

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20**

| 1215Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO- Paracetamol/Codeine 500/30 [TX] | [a] APX-Paracetamol/Codeine [TY] |
| | | | | | | [a] Codalgin Forte [AF] | [a] Codapane Forte 500/30 [AL] |
| | | | | | | [a] Comfarol Forte [SZ] | [a] Paracetamol/Codeine GH 500/30 [GQ] |
| | | | | | | [a] Prodeine Forte [AV] | |
| | | | [B]3.81 | 20.91 | 18.64 | [a] Panadeine Forte [SW] | |

***Other opioids***

## TAPENTADOL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority Required (STREAMLINED)**

***10755***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***10748***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***10752***

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**tapentadol 50 mg modified release tablet, 28**

| 10096J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 30.09 | 25.00 | Palexia SR [CS] |

**tapentadol 100 mg modified release tablet, 28**

| 10094G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 36.98 | 25.00 | Palexia SR [CS] |

**tapentadol 150 mg modified release tablet, 28**

| 10100N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 43.59 | 25.00 | Palexia SR [CS] |

**tapentadol 200 mg modified release tablet, 28**

| 10091D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 49.44 | 25.00 | Palexia SR [CS] |

**tapentadol 250 mg modified release tablet, 28**

| 10092E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 54.39 | 25.00 | Palexia SR [CS] |

## TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

***10768***

Severe pain

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**tramadol hydrochloride 50 mg capsule, 20**

| 5232J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Tramadol [TX] | [a] Tramadol Sandoz [SZ] |
| | | | | | | [a] TRAMADOL-WGR [WG] | [a] Tramedo [AF] |
| | | | | | | [a] Zydol [RW] | |
| | | | [B]2.25 | 19.35 | 18.64 | [a] Tramal [CS] | |

**tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules**

| 5231H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.75 | 19.29 | [a] Tramadol AN [JU] | [a] Tramadol Sandoz [SZ] |
| | | | | | | [a] Tramal 100 [CS] | |

**tramadol hydrochloride 100 mg/mL oral liquid, 10 mL**

| 5150C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 20.51 | 22.05 | Tramal [CS] |

## TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

***10766***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**tramadol hydrochloride 50 mg capsule, 20**

| 12024W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 0.5 | 0 | 0.00 | *17.60 | 19.14 | [a] APO-Tramadol [TX] | [a] Tramadol Sandoz [SZ] |
| | | | | | | [a] TRAMADOL-WGR [WG] | [a] Tramedo [AF] |
| | | | | | | [a] Zydol [RW] | |
| | | | [B]1.39 | 18.99 | 19.14 | [a] Tramal [CS] | |

## TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***16276***

Severe pain

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is sharing the post-operative care of the patient with a medical practitioner.

**tramadol hydrochloride 50 mg capsule, 20**

| 12008B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 0.5 | 0 | 0.00 | *17.60 | 19.14 | [a] APO-Tramadol [TX] | [a] Tramadol Sandoz [SZ] |
| | | | | | | [a] TRAMADOL-WGR [WG] | [a] Tramedo [AF] |
| | | | | | | [a] Zydol [RW] | |
| | | | [B]1.39 | 18.99 | 19.14 | [a] Tramal [CS] | |

## TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Restricted benefit**

***10771***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10772***

Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

***10764***

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**tramadol hydrochloride 50 mg capsule, 20**

| 8455B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Tramadol [TX] | [a] Tramadol Sandoz [SZ] |
| | | | | | | [a] TRAMADOL-WGR [WG] | [a] Tramedo [AF] |
| | | | | | | [a] Zydol [RW] | |
| | | | [B]2.25 | 19.35 | 18.64 | [a] Tramal [CS] | |

**tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules**

| 8582Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 17.75 | 19.29 | [a] Tramadol AN [JU] | [a] Tramadol Sandoz [SZ] |
| | | | | | | [a] Tramal 100 [CS] | |

**tramadol hydrochloride 100 mg/mL oral liquid, 10 mL**

| 8843K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 20.51 | 22.05 | Tramal [CS] |

## TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority Required (STREAMLINED)**

***10755***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***10748***

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority Required (STREAMLINED)**

***10752***

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**tramadol hydrochloride 50 mg modified release tablet, 20**

| 2527B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 18.03 | 19.57 | Tramal SR 50 [CS] |

**tramadol hydrochloride 100 mg modified release tablet, 20**

| 8523N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 17.34 | 18.88 | [a] APO-Tramadol SR [TX] | [a] Tramadol Sandoz SR [SZ] |
| | | | | | | [a] Tramadol SR generichealth [GQ] | [a] TRAMADOL-WGR SR [WG] |
| | | | | | | [a] Tramedo SR [AL] | [a] Zydol SR 100 [RW] |
| | | | [B]4.24 | 21.58 | 18.88 | [a] Tramal SR 100 [CS] | |

**tramadol hydrochloride 150 mg modified release tablet, 20**

| 8524P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 18.10 | 19.64 | [a] APO-Tramadol SR [TX] | [a] Tramadol Sandoz SR [SZ] |
| | | | | | | [a] Tramadol SR generichealth [GQ] | [a] TRAMADOL-WGR SR [WG] |
| | | | | | | [a] Tramedo SR [AL] | [a] Zydol SR 150 [RW] |
| | | | [B]5.13 | 23.23 | 19.64 | [a] Tramal SR 150 [CS] | |

**tramadol hydrochloride 200 mg modified release tablet, 20**

| 8525Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 18.26 | 19.80 | [a] APO-Tramadol SR [TX] | [a] Tramadol Sandoz SR [SZ] |
| | | | | | | [a] Tramadol SR generichealth [GQ] | [a] TRAMADOL-WGR SR [WG] |
| | | | | | | [a] Tramedo SR [AL] | [a] Zydol SR 200 [RW] |
| | | | [B]5.82 | 24.08 | 19.80 | [a] Tramal SR 200 [CS] | |

## OTHER ANALGESICS AND ANTIPYRETICS

### *Anilides*

## PARACETAMOL

**Restricted benefit**

***5835***

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

### paracetamol 48 mg/mL oral liquid, 200 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1770E NP | ‡1 | 2 | 0.00 | 18.04 | 19.58 | Panamax 240 Elixir [SW] |

### paracetamol 500 mg tablet, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1746X NP | 1 | 1 | 0.00 | 16.13 | 17.67 | [a] APO-Paracetamol [TX] | [a] Febridol [XT] |
| | | | | | | [a] Panamax [SW] | [a] Paracetamol (Sandoz) [SZ] |
| | | | | | | [a] Paracetamol Sandoz Pharma [QS] | [a] Paralgin [OW] |
| | | | | | | [a] PHARMACY CARE PARACETAMOL [SI] | [a] Wagner Health Paracetamol [BG] |

## PARACETAMOL

**Restricted benefit**

***5846***

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

### paracetamol 48 mg/mL oral liquid, 200 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3349G DP | ‡1 | 0 | 0.00 | 18.04 | 19.58 | Panamax 240 Elixir [SW] |

### paracetamol 500 mg tablet, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5196L DP | 1 | 0 | 0.00 | 16.13 | 17.67 | [a] APO-Paracetamol [TX] | [a] Febridol [XT] |
| | | | | | | [a] Panamax [SW] | [a] Paracetamol (Sandoz) [SZ] |
| | | | | | | [a] Paracetamol Sandoz Pharma [QS] | [a] Paralgin [OW] |
| | | | | | | [a] PHARMACY CARE PARACETAMOL [SI] | [a] Wagner Health Paracetamol [BG] |

## PARACETAMOL

**Restricted benefit**

***5885***

Chronic arthropathies

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

### paracetamol 500 mg tablet, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5224Y DP | 3 | 0 | 0.00 | *19.68 | 21.22 | [a] APO-Paracetamol [TX] | [a] Febridol [XT] |
| | | | | | | [a] Panamax [SW] | [a] Paracetamol (Sandoz) [SZ] |
| | | | | | | [a] Paracetamol Sandoz Pharma [QS] | [a] Paralgin [OW] |
| | | | | | | [a] PHARMACY CARE PARACETAMOL [SI] | [a] Wagner Health Paracetamol [BG] |

## PARACETAMOL

**Restricted benefit**

***5865***

Chronic arthropathies

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

### paracetamol 500 mg tablet, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8784H NP | 3 | 4 | 0.00 | *19.68 | 21.22 | [a] APO-Paracetamol [TX] | [a] Febridol [XT] |
| | | | | | | [a] Panamax [SW] | [a] Paracetamol (Sandoz) [SZ] |
| | | | | | | [a] Paracetamol Sandoz Pharma [QS] | [a] Paralgin [OW] |
| | | | | | | [a] PHARMACY CARE PARACETAMOL [SI] | [a] Wagner Health Paracetamol [BG] |

## PARACETAMOL

**Restricted benefit**

***6280***

Persistent pain

**Clinical criteria:**

- The condition must be associated with osteoarthritis.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**Note** Pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 96 and pharmaceutical benefits that have the form paracetamol 665 mg modified release tablet, 192 are equivalent for the purposes of substitution.

### paracetamol 665 mg modified release tablet, 96

| 8814X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *21.84 | 23.38 | [a] APOHEALTH Osteo Relief Paracetamol 665 mg [TX] | [a] Chemists' Own Osteo Relief Paracetamol [RF] |
| | | | | | | [a] Osteomol 665 Paracetamol [CR] | [a] Parapane OSTEO [XT] |
| | | | | | | [a] Pharmacy Action Paracetamol Osteo 665 [GQ] | |

### paracetamol 665 mg modified release tablet, 192

| 10797G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.66 | 23.20 | [a] Osteomol 665 Paracetamol [CR] | [a] Parapane OSTEO [XT] |

## *Gabapentinoids*

## PREGABALIN

**Authority Required (STREAMLINED)**

***4172***

Neuropathic pain

**Clinical criteria:**

- The condition must be refractory to treatment with other drugs.

### pregabalin 25 mg capsule, 56

| 2348N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.33 | 19.87 | [a] APO-Pregabalin [TX] | [a] BTC Pregabalin [BG] |
| | | | | | | [a] Lyzalon [AF] | [a] Neuroccord [CR] |
| | | | | | | [a] Prebalin [RF] | [a] PREGABALIN-DRLA [RZ] |
| | | | | | | [a] Pregabalin Lupin [HQ] | [a] Pregabalin Sandoz [SZ] |
| | | | | | | [a] PREGABALIN-WGR [WG] | |
| | | | [B]1.99 | 20.32 | 19.87 | [a] Lyrica [GO] | |

### pregabalin 75 mg capsule, 56

| 2335X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Pregabalin [TX] | [a] BTC Pregabalin [BG] |
| | | | | | | [a] Lyzalon [AF] | [a] Neuroccord [CR] |
| | | | | | | [a] Prebalin [RF] | [a] PREGABALIN-DRLA [RZ] |
| | | | | | | [a] Pregabalin Lupin [HQ] | [a] Pregabalin Sandoz [SZ] |
| | | | | | | [a] PREGABALIN-WGR [WG] | |
| | | | [B]5.07 | 23.67 | 20.14 | [a] Lyrica [GO] | |

### pregabalin 150 mg capsule, 56

| 2355Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.56 | 22.10 | [a] APO-Pregabalin [TX] | [a] BTC Pregabalin [BG] |
| | | | | | | [a] Lyzalon [AF] | [a] Neuroccord [CR] |
| | | | | | | [a] Prebalin [RF] | [a] PREGABALIN-DRLA [RZ] |
| | | | | | | [a] Pregabalin Lupin [HQ] | [a] Pregabalin Sandoz [SZ] |
| | | | | | | [a] PREGABALIN-WGR [WG] | |
| | | | [B]6.49 | 27.05 | 22.10 | [a] Lyrica [GO] | |

### pregabalin 300 mg capsule, 56

| 2363J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 23.59 | 25.00 | [a] APO-Pregabalin [TX] | [a] BTC Pregabalin [BG] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2363J | | | | | | [a] Lyzalon [AF] | [a] Neuroccord [CR] |
| | | | | | | [a] Prebalin [RF] | [a] PREGABALIN-DRLA [RZ] |
| | | | | | | [a] Pregabalin Lupin [HQ] | [a] Pregabalin Sandoz [SZ] |
| | | | | | | [a] PREGABALIN-WGR [WG] | |
| | | | [B]1.61 | 25.20 | 25.00 | [a] Lyrica [GO] | |

## ANTIMIGRAINE PREPARATIONS

### *Selective serotonin (5HT1) agonists*

### ELETRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***5141***

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**eletriptan 40 mg tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5290K NP | 1 | 5 | 0.00 | 27.59 | 25.00 | Relpax [GO] |

**eletriptan 80 mg tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5291L NP | 1 | 5 | 0.00 | 27.59 | 25.00 | Relpax [GO] |

### NARATRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4562***

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**naratriptan 2.5 mg tablet, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8298R NP | 2 | 5 | 0.00 | *26.22 | 25.00 | Naramig [AS] |

### NARATRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***5859***

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom adverse events have occurred with other suitable PBS-listed drugs.

**Authority Required**

***5887***

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions have occurred with other suitable PBS-listed drugs.

**Authority Required**

***5860***

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom drug interactions are expected to occur with other suitable PBS-listed drugs.

**Authority Required**

***5849***

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance.

**Authority Required**

***5850***

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past, **AND**
- Patient must be one in whom transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.

**naratriptan 2.5 mg tablet, 2**

| 9734H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *26.22 | 25.00 | Naramig [AS] |

## RIZATRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** Pharmaceutical benefits that have the form rizatriptan wafer 10 mg (as benzoate) and pharmaceutical benefits that have the form rizatriptan tablet (orally disintegrating) 10 mg (as benzoate) are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***5141***

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**rizatriptan 10 mg wafer, 2**

| 9313E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | [B]3.34 | *26.18 | 24.38 | [a] Rizatriptan Wafers-10mg [AF] | |
| | | | [B]4.52 | *27.36 | 24.38 | [a] Maxalt [AL] | |

**rizatriptan 10 mg orally disintegrating tablet, 2**

| 10551H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-RIZATRIPTAN ODT [TW] | [a] RIXALT [RF] |
| | | | | | | [a] Rizatriptan-Au [DZ] | [a] Rizatriptan ODT Viatris [MQ] |
| | | | | | | [a] RIZATRIPTAN ODT-WGR [WG] | |

## SUMATRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***5141***

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**sumatriptan 50 mg tablet, 4**

| 1849H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.41 | 21.95 | [a] APO-Sumatriptan [TX] | [a] Iptam [AL] |
| | | | | | | [a] Pharmacor Sumatriptan 50 [CR] | [a] Sumatran [OW] |
| | | | | | | [a] Sumatriptan generichealth [GQ] | [a] Sumatriptan Sandoz [SZ] |

| 1849H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] SUMATRIPTAN-WGR [WG] | |
| | | | [B]4.07 | 24.48 | 21.95 | [a] Imigran [LN] | |

**sumatriptan 50 mg tablet, 2**

| 8144P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *20.64 | 22.18 | [a] APO-Sumatriptan [TX] | [a] Iptam [AL] |
| | | | | | | [a] Sumagraine Migraine Relief [GQ] | [a] Sumatran [OW] |

**SUMATRIPTAN Tablet 50 mg (base) (fast disintegrating), 4**

| 10694W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 4.07 | 24.48 | 21.95 | [a] Imigran FDT [AS] |

## ZOLMITRIPTAN

**Caution** Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***5141***

Migraine attack

**Clinical criteria:**

- The condition must have usually failed to respond to analgesics in the past.

**zolmitriptan 2.5 mg tablet, 2**

| 8266C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *25.88 | 25.00 | [a] APO-Zolmitriptan [TX] | [a] Zoltrip [RW] |
| | | | | | | [a] Zomig [AS] | |

### *Calcitonin gene-related peptide (CGRP) antagonists*

## EPTINEZUMAB

**Note** Eptinezumab at a dose of 300 mg, once every twelve weeks, is not subsidised on the PBS.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16018***

Chronic migraine

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist; **OR**
- Must be treated by a general practitioner in consultation with a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition, **AND**
- Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

Patient must have the number of migraine days per month documented in their medical records.

**eptinezumab 100 mg/mL injection, 1 mL vial**

| 13342F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 1,444.65 | 25.00 | Vyepti [LU] |

## EPTINEZUMAB

**Note** Eptinezumab at a dose of 300 mg, once every twelve weeks, is not subsidised on the PBS.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***12029***

Chronic migraine

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist neurologist or in consultation with a specialist neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month, **AND**
- Patient must continue to be appropriately managed for medication overuse headache.

Patient must have the number of migraine days per month documented in their medical records.

### eptinezumab 100 mg/mL injection, 1 mL vial

13352R

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 1,444.65 | 25.00 | Vyepti [LU] |

## FREMANEZUMAB

**Note** Pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL syringes and pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***14563***

Treatment-resistant migraine

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a neurologist; **OR**
- Must be treated by a general practitioner in consultation with a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained at least 50% reduction from baseline in the number of migraine headache days per month, **AND**
- Patient must continue to be appropriately managed for medication overuse headache.

Patient must have the number of migraine headache days per month documented in their medical records.

### fremanezumab 225 mg/1.5 mL injection, 1.5 mL syringe

12603H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 366.54 | 25.00 | [a] Ajovy [TB] |

### fremanezumab 225 mg/1.5 mL injection, 1.5 mL pen device

13129B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 366.54 | 25.00 | [a] Ajovy [TB] |

## FREMANEZUMAB

**Note** Pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL syringes and pharmaceutical benefits that have the form fremanezumab 225 mg/1.5 mL pen devices are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16104***

Treatment-resistant migraine

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist; **OR**
- Must be treated by a general practitioner in consultation with a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have experienced at least 8 migraine headache days per month, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition, **AND**
- Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

Patient must have the number of migraine headache days per month documented in their medical records.

### fremanezumab 225 mg/1.5 mL injection, 1.5 mL syringe

| 12611R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 366.54 | 25.00 | [a] Ajovy [TB] |

### fremanezumab 225 mg/1.5 mL injection, 1.5 mL pen device

| 13115G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 366.54 | 25.00 | [a] Ajovy [TB] |

## GALCANEZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***14563***

Treatment-resistant migraine

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a neurologist; **OR**
- Must be treated by a general practitioner in consultation with a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved and maintained at least 50% reduction from baseline in the number of migraine headache days per month, **AND**
- Patient must continue to be appropriately managed for medication overuse headache.

Patient must have the number of migraine headache days per month documented in their medical records.

### galcanezumab 120 mg/mL injection, 1 mL pen device

| 12469G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 516.42 | 25.00 | Emgality [LY] |

## GALCANEZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16104***

Treatment-resistant migraine

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist; **OR**
- Must be treated by a general practitioner in consultation with a neurologist, **AND**
- Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.

**Clinical criteria:**

- Patient must have experienced at least 8 migraine headache days per month, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition, **AND**
- Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

Patient must have the number of migraine headache days per month documented in their medical records.

**galcanezumab 120 mg/mL injection, 1 mL pen device**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12478R | 2 | 1 | 0.00 | *1,023.48 | 25.00 | Emgality [LY] |

### *Other antimigraine preparations*

## PIZOTIFEN

**pizotifen 500 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3074T NP | 1 | 2 | 0.00 | 25.62 | 25.00 | Sandomigran 0.5 [AE] |

## PIZOTIFEN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pizotifen 500 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13866T NP | 2 | 2 | 0.00 | *36.88 | 25.00 | Sandomigran 0.5 [AE] |

# ANTIEPILEPTICS

## ANTIEPILEPTICS

### *Barbiturates and derivatives*

## PHENOBARBITAL

**Restricted benefit**

***16520***

Epilepsy

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**phenobarbital 200 mg (equivalent to phenobarbital sodium 219 mg)/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2138M NP | 1 | 0 | 0.00 | 36.70 | 25.00 | Phenobarbitone Injection (Aspen Pharmacare Australia Pty Ltd) [AS] |

## PHENOBARBITAL

**Note** Pharmaceutical benefits that have the brand Phenobarbital Tablets, USP 30 mg (Rising Pharmaceuticals, USA) can be substituted for Phenobarb in the case of a shortage.

**Restricted benefit**

***16520***

Epilepsy

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**phenobarbital 30 mg tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1850J NP | 1 | 4 | 0.00 | 19.80 | 21.34 | [a] Phenobarb [RW] |

**phenobarbital 30 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15415H NP | 2 | 4 | 0.00 | *225.84 | 25.00 | [a] Phenobarbital Tablets, USP 30 mg (Rising Pharmaceuticals, USA) [DZ] |

## PRIMIDONE

**Restricted benefit**

***16524***
For prescribing by certain health practitioners
**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**primidone 250 mg tablet, 200**

| 1939C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 69.56 | 25.00 | Mysoline [LM] |

## *Hydantoin derivatives*

### PHENYTOIN

**Restricted benefit**
***16524***
For prescribing by certain health practitioners
**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**phenytoin sodium 30 mg capsule, 200**

| 1873N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 52.74 | 25.00 | Dilantin Sodium [GO] |

**phenytoin 30 mg/5 mL oral liquid, 500 mL**

| 2692Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 3 | 0.00 | 27.08 | 25.00 | Dilantin [GO] |

**phenytoin 50 mg chewable tablet, 200**

| 1249R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 64.98 | 25.00 | Dilantin Infatabs [GO] |

**phenytoin sodium 100 mg capsule, 200**

| 1874P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 34.07 | 25.00 | Dilantin Sodium [GO] |

### PHENYTOIN

**Restricted benefit**
***16493***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.
**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**phenytoin sodium 30 mg capsule, 200**

| 14015P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *91.12 | 25.00 | Dilantin Sodium [GO] |

**phenytoin 30 mg/5 mL oral liquid, 500 mL**

| 13841L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 3 | 0.00 | *39.80 | 25.00 | Dilantin [GO] |

**phenytoin 50 mg chewable tablet, 200**

| 13894G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *115.66 | 25.00 | Dilantin Infatabs [GO] |

**phenytoin sodium 100 mg capsule, 200**

| 13972J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *53.78 | 25.00 | Dilantin Sodium [GO] |

## *Succinimide derivatives*

### ETHOSUXIMIDE

**Restricted benefit**
***16524***
For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**ethosuximide 250 mg capsule, 100**

| 11703Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *288.60 | 25.00 | ZARONTIN [IX] |

**ethosuximide 250 mg/5 mL oral liquid, 200 mL**

| 1414K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 73.13 | 25.00 | Zarontin [IX] |

## ETHOSUXIMIDE

**Restricted benefit**

***16493***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**ethosuximide 250 mg/5 mL oral liquid, 200 mL**

| 14014N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *132.78 | 25.00 | Zarontin [IX] |

### *Benzodiazepine derivatives*

## CLONAZEPAM

**Restricted benefit**

***16520***

Epilepsy

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack**

| 1807D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 24.61 | 25.00 | Rivotril [PB] |

## CLONAZEPAM

**Caution** Abuse of clonazepam has been reported. Refer to the current product information.

**Authority Required**

***16517***

Epilepsy

**Clinical criteria:**

- The condition must be neurologically proven.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**clonazepam 2 mg tablet, 100**

| 1806C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *32.78 | 25.00 | Paxam 2 [AF] |

**clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL**

| 1808E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *21.84 | 23.38 | Rivotril [PB] |

## CLONAZEPAM

**Caution** Abuse of clonazepam has been reported. Refer to the current product information.

**Note** Pharmaceutical benefits that have form pack size clonazepam 500 microgram tablet, 100 and clonazepam 500 microgram tablet, 50 are equivalent for the purposes of substitution.

**Authority Required**

***16517***

Epilepsy

**Clinical criteria:**

- The condition must be neurologically proven.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**clonazepam 500 microgram tablet, 100**

| 1805B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *27.50 | 25.00 | [a] Paxam 0.5 [AF] |

**clonazepam 500 microgram tablet, 50**

| 11559J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 2 | 3.44 | *31.36 | 25.00 | [a] Rivotril [PB] |

## NITRAZEPAM

**Authority Required**

***16653***

Myoclonic epilepsy

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required**

***16692***

Malignant neoplasia (late stage)

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required**

***5950***

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority Required**

***5941***

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**nitrazepam 5 mg tablet, 25**

| 2732T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Alodorm [AF] | [a] Mogadon [IL] |

### *Carboxamide derivatives*

## CARBAMAZEPINE

**carbamazepine 100 mg tablet, 100**

| 5039F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 2 | 0 | 0.00 | *27.32 | 25.00 | [a] AVLOIRE [VQ] | |
| | | | [B]1.60 | *28.92 | 25.00 | [a] Tegretol 100 [NV] | |

**carbamazepine 100 mg/5 mL oral liquid, 300 mL**

| 5041H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 30.47 | 25.00 | Tegretol Liquid [NV] |

**carbamazepine 200 mg tablet, 100**

| 1724R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 2 | 0 | 0.00 | *35.86 | 25.00 | [a] AVLOIRE [VQ] | [a] Tegretol 200 [NV] |

**carbamazepine 200 mg modified release tablet, 100**

| 14671E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | 0 | 0.00 | *36.32 | 25.00 | Tegretol CR 200 [NV] |

**carbamazepine 400 mg modified release tablet, 100**

| 14680P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 2 | 0 | 0.00 | *56.08 | 25.00 | Tegretol CR 400 [NV] |

## CARBAMAZEPINE

**Restricted benefit**

***16524***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**carbamazepine 100 mg tablet, 100**

| 2422L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *27.32 | 25.00 | [a] AVLOIRE [VQ] | |
| | | | [B]1.60 | *28.92 | 25.00 | [a] Tegretol 100 [NV] | |

**carbamazepine 100 mg/5 mL oral liquid, 300 mL**

| 2427R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 30.47 | 25.00 | Tegretol Liquid [NV] |

**carbamazepine 200 mg tablet, 100**

| 1706T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *35.86 | 25.00 | [a] AVLOIRE [VQ] | [a] Tegretol 200 [NV] |

**carbamazepine 200 mg modified release tablet, 100**

| 14681Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *36.32 | 25.00 | Tegretol CR 200 [NV] |

**carbamazepine 400 mg modified release tablet, 100**

| 14666X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *56.08 | 25.00 | Tegretol CR 400 [NV] |

## CARBAMAZEPINE

**Restricted benefit**

***16493***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**carbamazepine 100 mg tablet, 100**

| 14509P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *40.28 | 25.00 | [a] AVLOIRE [VQ] | |
| | | | [B]3.20 | *43.48 | 25.00 | [a] Tegretol 100 [NV] | |

**carbamazepine 100 mg/5 mL oral liquid, 300 mL**

| 14051M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *46.58 | 25.00 | Tegretol Liquid [NV] |

**carbamazepine 200 mg tablet, 100**

| 14338P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *57.36 | 25.00 | [a] AVLOIRE [VQ] | [a] Tegretol 200 [NV] |

**carbamazepine 200 mg modified release tablet, 100**

| 14673G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *58.28 | 25.00 | Tegretol CR 200 [NV] |

**carbamazepine 400 mg modified release tablet, 100**

| 14662Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *97.80 | 25.00 | Tegretol CR 400 [NV] |

## OXCARBAZEPINE

**Authority Required (STREAMLINED)**

***17478***

Seizures

**Clinical criteria:**

- Patient must have focal onset seizures; **OR**
- Patient must have primary generalised tonic-clonic seizures, **AND**
- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**oxcarbazepine 60 mg/mL oral liquid, 250 mL**

| 8588B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *98.22 | 25.00 | Trileptal [NV] |

**oxcarbazepine 150 mg tablet, 100**

| 8584T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 56.29 | 25.00 | Trileptal [NV] |

**oxcarbazepine 300 mg tablet, 100**

| 8585W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 83.55 | 25.00 | Trileptal [NV] |

**oxcarbazepine 600 mg tablet, 100**

| 8586X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 130.75 | 25.00 | Trileptal [NV] |

## OXCARBAZEPINE

**Authority Required (STREAMLINED)**

***17509***

Seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have focal onset seizures; **OR**
- Patient must have primary generalised tonic-clonic seizures, **AND**
- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**oxcarbazepine 60 mg/mL oral liquid, 250 mL**

| 13936L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *185.48 | 25.00 | Trileptal [NV] |

**oxcarbazepine 150 mg tablet, 100**

| 14562K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *98.22 | 25.00 | Trileptal [NV] |

**oxcarbazepine 300 mg tablet, 100**

| 14033N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *154.66 | 25.00 | Trileptal [NV] |

**oxcarbazepine 600 mg tablet, 100**

| 13935K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *252.14 | 25.00 | Trileptal [NV] |

### *Fatty acid derivatives*

## TIAGABINE

**Authority Required (STREAMLINED)**

***17445***
Focal onset seizures
**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**tiagabine 5 mg tablet, 50**

| 8221Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *61.78 | 25.00 | Gabitril [TB] |

**tiagabine 10 mg tablet, 50**

| 8222R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *109.22 | 25.00 | Gabitril [TB] |

**tiagabine 15 mg tablet, 50**

| 8223T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *152.60 | 25.00 | Gabitril [TB] |

## TIAGABINE

**Authority Required (STREAMLINED)**
***17444***
Focal onset seizures
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**tiagabine 5 mg tablet, 50**

| 13892E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *109.20 | 25.00 | Gabitril [TB] |

**tiagabine 10 mg tablet, 50**

| 13947C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *208.56 | 25.00 | Gabitril [TB] |

**tiagabine 15 mg tablet, 50**

| 13893F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *295.84 | 25.00 | Gabitril [TB] |

## VALPROATE

**Caution** There are reports of fatal hepatotoxicity, particularly in children.
There is increasing evidence of dose-related teratogenesis from this drug.

**Restricted benefit**
***16524***
For prescribing by certain health practitioners
**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**valproate sodium 100 mg tablet, 100**

| 2294R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *35.92 | 25.00 | Epilim [SW] |

**valproate sodium 200 mg enteric tablet, 100**

| 2289L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *25.08 | 25.00 | [a] APO-Sodium Valproate [TX] | [a] Sodium Valproate Sandoz [SZ] |
| | | | | | | [a] Valproate Winthrop EC 200 [WA] | [a] Valpro EC 200 [AF] |
| | | | [B]1.78 | 26.86 | 25.00 | [a] Epilim EC [SW] | |

**valproate sodium 200 mg/5 mL oral liquid, 300 mL**

| 2293Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *42.32 | 25.00 | Epilim Liquid [SW] |

**valproate sodium 200 mg/5 mL oral liquid, 300 mL**

| 2295T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *42.32 | 25.00 | Epilim Syrup [SW] |

**valproate sodium 500 mg enteric tablet, 100**

| 2290M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *35.12 | 25.00 | [a] APO-Sodium Valproate [TX] | [a] Sodium Valproate Sandoz [SZ] |
| | | | | | | [a] Valproate Winthrop EC 500 [WA] | [a] Valpro EC 500 [AF] |
| | | | [B]1.76 | 36.88 | 25.00 | [a] Epilim EC [SW] | |

## VALPROATE

**Caution** There are reports of fatal hepatotoxicity, particularly in children.

There is increasing evidence of dose-related teratogenesis from this drug.

**Restricted benefit**

***16493***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**valproate sodium 100 mg tablet, 100**

| 13840K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *57.48 | 25.00 | Epilim [SW] |

**valproate sodium 200 mg enteric tablet, 100**

| 14017R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *35.80 | 25.00 | [a] APO-Sodium Valproate [TX] | [a] Sodium Valproate Sandoz [SZ] |
| | | | | | | [a] Valproate Winthrop EC 200 [WA] | [a] Valpro EC 200 [AF] |
| | | | [B]3.56 | 39.36 | 25.00 | [a] Epilim EC [SW] | |

**valproate sodium 200 mg/5 mL oral liquid, 300 mL**

| 13950F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *70.28 | 25.00 | Epilim Syrup [SW] |

**valproate sodium 200 mg/5 mL oral liquid, 300 mL**

| 13973K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *70.28 | 25.00 | Epilim Liquid [SW] |

**valproate sodium 500 mg enteric tablet, 100**

| 13917L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 2 | 0.00 | *55.88 | 25.00 | [a] APO-Sodium Valproate [TX] | [a] Sodium Valproate Sandoz [SZ] |
| | | | | | | [a] Valproate Winthrop EC 500 [WA] | [a] Valpro EC 500 [AF] |
| | | | [B]3.52 | 59.40 | 25.00 | [a] Epilim EC [SW] | |

## VIGABATRIN

**Caution** Visual field defects have been reported with this drug.

**Authority Required (STREAMLINED)**

***17445***

Focal onset seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**vigabatrin 500 mg tablet, 100**

| 2667J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 85.91 | 25.00 | Sabril [SW] |

**vigabatrin 500 mg powder for oral liquid, 60 sachets**

| 2668K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 60.68 | 25.00 | Sabril [SW] |

## VIGABATRIN

**Caution** Visual field defects have been reported with this drug.

**Authority Required (STREAMLINED)**

***17444***

Focal onset seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**vigabatrin 500 mg tablet, 100**

| 13919N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *159.62 | 25.00 | Sabril [SW] |

**vigabatrin 500 mg powder for oral liquid, 60 sachets**

| 13974L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *107.00 | 25.00 | Sabril [SW] |

### *Other antiepileptics*

## BRIVARACETAM

**Authority Required (STREAMLINED)**

***17452***

Intractable focal onset seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with levetiracetam.

**brivaracetam 25 mg tablet, 56**

| 11327E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 153.74 | 25.00 | Briviact [UC] |

**brivaracetam 50 mg tablet, 56**

| 11338R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 153.74 | 25.00 | Briviact [UC] |

**brivaracetam 75 mg tablet, 56**

| 11350J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 153.74 | 25.00 | Briviact [UC] |

**brivaracetam 100 mg tablet, 56**

| 11357R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 153.74 | 25.00 | Briviact [UC] |

## BRIVARACETAM

**Authority Required (STREAMLINED)**

***17451***

Intractable focal onset seizures

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more antiseizure medications which include one second-line adjunctive agent, **AND**

- The condition must have failed to be controlled satisfactorily by other antiseizure medications, which include at least one first-line antiseizure agent and at least two second-line adjunctive antiseizure agents, **AND**
- The treatment must not be given concomitantly with levetiracetam, except for cross titration.

**brivaracetam 25 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11328F | 1 | 5 | 0.00 | 153.74 | 25.00 | Briviact [UC] |

**brivaracetam 50 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11334M | 1 | 5 | 0.00 | 153.74 | 25.00 | Briviact [UC] |

**brivaracetam 75 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11356Q | 1 | 5 | 0.00 | 153.74 | 25.00 | Briviact [UC] |

**brivaracetam 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11339T | 1 | 5 | 0.00 | 153.74 | 25.00 | Briviact [UC] |

## BRIVARACETAM

**Authority Required (STREAMLINED)**

***17561***

Intractable focal onset seizures

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more antiseizure medications which include one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other antiseizure medications, which include at least one first-line antiseizure agent and at least two second-line adjunctive antiseizure agents, **AND**
- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must not be given concomitantly with levetiracetam, except for cross titration.

**brivaracetam 10 mg/mL oral liquid, 300 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11349H | 1 | 5 | 0.00 | 189.83 | 25.00 | Briviact [UC] |

## BRIVARACETAM

**Authority Required (STREAMLINED)**

***17540***

Intractable focal onset seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must not be given concomitantly with levetiracetam.

**brivaracetam 10 mg/mL oral liquid, 300 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11358T NP | 1 | 5 | 0.00 | 189.83 | 25.00 | Briviact [UC] |

## CANNABIDIOL

**Note** Requests for increased quantities may be sought based on daily doses not exceeding 20 mg/kg/day (in line with the Product Information) for up to 4 weeks per dispensing.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17678***

Seizures of the Lennox-Gastaut syndrome

**Clinical criteria:**

- Patient must have a diagnosis of Lennox-Gastaut syndrome; the diagnosis should be confirmed by an electroencephalogram (EEG) where possible, **AND**
- Patient must have (as an initiating patient)/have had (as a continuing patient) more than one type of seizure that is not adequately controlled with at least two other antiseizure medications prior to initiating treatment with this medicine, **AND**
- The treatment must be as adjunctive therapy to other antiseizure medication.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a neurologist, (ii) a paediatrician if treatment is being initiated; **OR**
- Must be treated by a prescriber who is either: (i) a neurologist, (ii) a paediatrician if treatment is being continued or re-initiated; **OR**
- Must be treated by a general practitioner in consultation with either: (i) a neurologist, (ii) a paediatrician if treatment is being continued.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

**cannabidiol 100 mg/mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13277T | 1 | 5 | 0.00 | 1,532.91 | 25.00 | Epidyolex [JA] |

## CANNABIDIOL

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Requests for increased quantities may be sought based on daily doses not exceeding 20 mg/kg/day (in line with the Product Information) for up to 4 weeks per dispensing.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17521***

Severe myoclonic epilepsy in infancy (Dravet syndrome)

**Clinical criteria:**

- Patient must have (as an initiating patient)/have had (as a continuing patient), generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other antiseizure medications, **AND**
- The treatment must be as adjunctive therapy to at least two other antiseizure medications.

**Treatment criteria:**

- Must be treated by a neurologist if treatment is being initiated; **OR**
- Must be treated by a neurologist if treatment is being continued or re-initiated; **OR**
- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; **OR**
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

**cannabidiol 100 mg/mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12467E | 1 | 5 | 0.00 | 1,532.91 | 25.00 | Epidyolex [JA] |

## FENFLURAMINE

**Note** Cardiac monitoring must be carried out in accordance with the approved Product Information while on treatment with this drug for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17457***

Severe myoclonic epilepsy in infancy (Dravet syndrome)

**Clinical criteria:**

- Patient must have (if initiating) generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other antiseizure medications; **OR**
- Patient must have had (if continuing) generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other antiseizure medications, **AND**
- The treatment must be as adjunctive therapy to at least two other antiseizure medications.

**Treatment criteria:**

- Must be treated by a neurologist if treatment is being initiated; **OR**
- Must be treated by a neurologist if treatment is being continued or re-initiated; **OR**
- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; **OR**
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

**fenfluramine hydrochloride 2.2 mg/mL oral liquid, 360 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14833Q | ‡1 | 5 | 0.00 | 4,696.70 | 25.00 | Fintepla [UC] |

## GABAPENTIN

**Authority Required (STREAMLINED)**

***17445***

Focal onset seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**gabapentin 100 mg capsule, 100**

| 8505P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.36 | 19.90 | [a] APX-Gabapentin [GX] | [a] Gabacor [CR] |
| | | | | | | [a] GAPENTIN [RF] | [a] Nupentin 100 [AF] |
| | | | [B]2.17 | 20.53 | 19.90 | [a] Neurontin [GO] | |

**gabapentin 300 mg capsule, 100**

| 1834M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 23.72 | 25.00 | [a] APX-Gabapentin [GX] | [a] Gabacor [CR] |
| | | | | | | [a] Gabapentin Sandoz [SZ] | [a] GABAPENTIN-WGR [WG] |
| | | | | | | [a] GAPENTIN [RF] | [a] Nupentin 300 [AF] |
| | | | [B]2.12 | 25.84 | 25.00 | [a] Neurontin [GO] | |

**gabapentin 400 mg capsule, 100**

| 1835N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 27.12 | 25.00 | [a] APX-Gabapentin [GX] | [a] Gabacor [CR] |
| | | | | | | [a] Gabapentin Sandoz [SZ] | [a] GABAPENTIN-WGR [WG] |
| | | | | | | [a] GAPENTIN [RF] | [a] Nupentin 400 [AF] |
| | | | [B]2.13 | 29.25 | 25.00 | [a] Neurontin [GO] | |

**gabapentin 600 mg tablet, 100**

| 8559L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 34.34 | 25.00 | [a] APX-GABAPENTIN [TX] | [a] GAPENTIN [RF] |
| | | | | | | [a] Pharmacor Gabapentin 600 [CR] | |
| | | | [B]2.14 | 36.48 | 25.00 | [a] Neurontin [GO] | |

**gabapentin 800 mg tablet, 100**

| 8389M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 41.35 | 25.00 | [a] APX-GABAPENTIN [XT] | [a] GAPENTIN [RF] |
| | | | | | | [a] Neurontin [GO] | [a] Pharmacor Gabapentin 800 [CR] |

## LACOSAMIDE

**Authority Required (STREAMLINED)**

***17541***

Intractable focal onset seizures

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more antiseizure medications which include one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other antiseizure medications, which include at least one first-line antiseizure agent and at least two second-line adjunctive antiseizure agents, **AND**
- The treatment must be for dose titration purposes.

**lacosamide 50 mg tablet, 14**

| 9333F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 20.31 | 21.85 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

**lacosamide 100 mg tablet, 14**

| 9334G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 1 | 1 | 0.00 | 26.27 | 25.00 | [a] LACOMED [DZ] | [a] Lacosamide Sandoz [SZ] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9334G | | | | | | [a] Vimcosa [CR] | [a] Vimpat [UC] |

**lacosamide 150 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9336J | 1 | 1 | 0.00 | 32.22 | 25.00 | [a] LACOMED [DZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

## LACOSAMIDE

**Authority Required (STREAMLINED)**

***17455***

Intractable focal onset seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**lacosamide 50 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10293R NP | 4 | 5 | 0.00 | *38.16 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

## LACOSAMIDE

**Authority Required (STREAMLINED)**

***17560***

Intractable focal onset seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**lacosamide 50 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14011K NP | 8 | 5 | 0.00 | *61.96 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

**lacosamide 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13867W NP | 2 | 5 | 0.00 | *109.64 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

## LACOSAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required (STREAMLINED)**

***17560***

Intractable focal onset seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**lacosamide 10 mg/mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14048J NP | ‡12 | 5 | 0.00 | *688.92 | 25.00 | [a] LACOMED [DZ] | [a] Vimpat [UC] |

**lacosamide 150 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14053P NP | 2 | 5 | 0.00 | *159.34 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |

| 14053P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

**lacosamide 200 mg tablet, 56**

| 13951G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *209.34 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

## LACOSAMIDE

**Authority Required (STREAMLINED)**

***17520***

Intractable focal onset seizures

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more antiseizure medications which include one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other antiseizure medications, which include at least one first-line antiseizure agent and at least two second-line adjunctive antiseizure agents.

**Authority Required (STREAMLINED)**

***17455***

Intractable focal onset seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**lacosamide 100 mg tablet, 56**

| 9335H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 62.00 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

## LACOSAMIDE

**Note** Requests for increases in the maximum quantity (packs) up to 3 times that stated may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17513***

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

**Treatment criteria:**

- Must be treated by a neurologist; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two antiseizure medications prior to when the drug is/was first commenced, **AND**
- The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised antiseizure medication at the time the drug is/was first commenced.

**lacosamide 10 mg/mL oral liquid, 200 mL**

| 12628P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *122.62 | 25.00 | [a] LACOMED [DZ] | [a] Vimpat [UC] |

## LACOSAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17515***

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures
Treatment Phase: Dose titration at the start of therapy, during therapy or to gradually cease treatment

**Treatment criteria:**

- Must be treated by a neurologist; **OR**
- Must be treated by a paediatrician.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two antiseizure medications prior to when the drug is/was first commenced, **AND**
- The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised antiseizure medication at the time the drug is/was first commenced, **AND**
- The treatment must be for dose titration purposes.

**lacosamide 100 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12633X | 1 | 1 | 0.00 | 26.27 | 25.00 | [a] LACOMED [DZ] | [a] Lacosamide Sandoz [SZ] |
| | | | | | | [a] Vimcosa [CR] | [a] Vimpat [UC] |

**lacosamide 150 mg tablet, 14**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12649R | 1 | 1 | 0.00 | 32.22 | 25.00 | [a] LACOMED [DZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

## LACOSAMIDE

**Note** Requests for increases in the maximum quantity (packs) up to 3 times that stated may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**
***17516***
Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a neurologist; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two antiseizure medications prior to when the drug is/was first commenced, **AND**
- The treatment must have been in combination with at least one PBS-subsidised antiseizure medication at the time the drug was first commenced.

**lacosamide 10 mg/mL oral liquid, 200 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14013M NP | ‡4 | 5 | 0.00 | *235.88 | 25.00 | [a] LACOMED [DZ] | [a] Vimpat [UC] |

## LACOSAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required (STREAMLINED)**
***17520***
Intractable focal onset seizures
Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be in combination with two or more antiseizure medications which include one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other antiseizure medications, which include at least one first-line antiseizure agent and at least two second-line adjunctive antiseizure agents.

**Authority Required (STREAMLINED)**
***17455***
Intractable focal onset seizures
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**lacosamide 10 mg/mL oral liquid, 200 mL**

| 11694L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡6 | 5 | 0.00 | *349.14 | 25.00 | [a] LACOMED [DZ] | [a] Vimpat [UC] |

**lacosamide 150 mg tablet, 56**

| 9337K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 85.78 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

**lacosamide 200 mg tablet, 56**

| 9338L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 109.59 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

## LACOSAMIDE

**Note** For dose titration involving the 100 mg or 150 mg strength, refer to the dose titration listing for these strengths with pack sizes of 14 units. Avoid prescribing a 'broken' quantity under this listing**.**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17513***

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

**Treatment criteria:**

- Must be treated by a neurologist; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two antiseizure medications prior to when the drug is/was first commenced, **AND**
- The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised antiseizure medication at the time the drug is/was first commenced.

**lacosamide 50 mg tablet, 14**

| 12626M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *38.16 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

**lacosamide 100 mg tablet, 56**

| 12634Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 62.00 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

**lacosamide 150 mg tablet, 56**

| 12627N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 85.78 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

**lacosamide 200 mg tablet, 56**

| 12658F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 109.59 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |

| 12658F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Vimpat [UC] | |

## LACOSAMIDE

**Note** For dose titration involving the 100 mg or 150 mg strength, refer to the dose titration listing for these strengths with pack sizes of 14 units. Avoid prescribing a 'broken' quantity under this listing.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***17516***

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a neurologist; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two antiseizure medications prior to when the drug is/was first commenced, **AND**
- The treatment must have been in combination with at least one PBS-subsidised antiseizure medication at the time the drug was first commenced.

### lacosamide 50 mg tablet, 14

| 14049K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *61.96 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

### lacosamide 100 mg tablet, 56

| 13839J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *109.64 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

### lacosamide 150 mg tablet, 56

| 13838H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *159.34 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

### lacosamide 200 mg tablet, 56

| 13949E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *209.34 | 25.00 | [a] LACOMED [DZ] | [a] Lacosam [AF] |
| | | | | | | [a] Lacosamide ARX [XT] | [a] Lacosamide Lupin [GQ] |
| | | | | | | [a] Lacosamide Sandoz [SZ] | [a] Vimcosa [CR] |
| | | | | | | [a] Vimpat [UC] | |

## LAMOTRIGINE

**Restricted benefit**

***17446***

Epileptic seizures

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**lamotrigine 5 mg tablet, 56**

| 8063J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.39 | 20.93 | Lamictal [AS] |

**lamotrigine 25 mg tablet, 56**

| 2848X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APX-Lamotrigine [TY] | [a] LAMITAN [RF] |
| | | | | | | [a] Lamotrigine GH [GQ] | [a] LAMOTRIGINE-WGR [WG] |
| | | | | | | [a] Logem [AL] | [a] Reedos 25 [ZS] |
| | | | | | | [a] Sandoz Lamotrigine [HX] | |
| | | | [B]4.08 | 22.68 | 20.14 | [a] Lamictal [AS] | |

**lamotrigine 50 mg tablet, 56**

| 2849Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.31 | 20.85 | [a] APX-Lamotrigine [TY] | [a] LAMITAN [RF] |
| | | | | | | [a] Lamotrigine GH [GQ] | [a] LAMOTRIGINE-WGR [WG] |
| | | | | | | [a] Logem [AL] | [a] Reedos 50 [ZS] |
| | | | | | | [a] Sandoz Lamotrigine [HX] | |
| | | | [B]3.44 | 22.75 | 20.85 | [a] Lamictal [AS] | |

**lamotrigine 100 mg tablet, 56**

| 2850B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 22.54 | 24.08 | [a] APX-Lamotrigine [TY] | [a] LAMITAN [RF] |
| | | | | | | [a] Lamotrigine GH [GQ] | [a] LAMOTRIGINE-WGR [WG] |
| | | | | | | [a] Logem [AL] | [a] Reedos 100 [ZS] |
| | | | | | | [a] Sandoz Lamotrigine [HX] | |
| | | | [B]3.45 | 25.99 | 24.08 | [a] Lamictal [AS] | |

**lamotrigine 200 mg tablet, 56**

| 2851C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 28.11 | 25.00 | [a] APX-Lamotrigine [TY] | [a] LAMITAN [RF] |
| | | | | | | [a] Lamotrigine GH [GQ] | [a] LAMOTRIGINE-WGR [WG] |
| | | | | | | [a] Logem [AL] | [a] Reedos 200 [ZS] |
| | | | | | | [a] Sandoz Lamotrigine [HX] | |
| | | | [B]3.46 | 31.57 | 25.00 | [a] Lamictal [AS] | |

## LAMOTRIGINE

**Restricted benefit**

***17512***

Epileptic seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**lamotrigine 5 mg tablet, 56**

| 14047H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.42 | 25.00 | Lamictal [AS] |

**lamotrigine 25 mg tablet, 56**

| 13842M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APX-Lamotrigine [TY] | [a] LAMITAN [RF] |
| | | | | | | [a] Lamotrigine GH [GQ] | [a] LAMOTRIGINE-WGR [WG] |
| | | | | | | [a] Logem [AL] | [a] Reedos 25 [ZS] |
| | | | | | | [a] Sandoz Lamotrigine [HX] | |
| | | | [B]8.16 | 31.00 | 24.38 | [a] Lamictal [AS] | |

**lamotrigine 50 mg tablet, 56**

| 13975M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.26 | 25.00 | [a] APX-Lamotrigine [TY] | [a] LAMITAN [RF] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13975M | | | | | | [a] Lamotrigine GH [GQ] | [a] LAMOTRIGINE-WGR [WG] |
| | | | | | | [a] Logem [AL] | [a] Reedos 50 [ZS] |
| | | | | | | [a] Sandoz Lamotrigine [HX] | |
| | | | [B]6.88 | 31.14 | 25.00 | [a] Lamictal [AS] | |

**lamotrigine 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14052N | | | | | | | |
| NP | 2 | 5 | 0.00 | *30.72 | 25.00 | [a] APX-Lamotrigine [TY] | [a] LAMITAN [RF] |
| | | | | | | [a] Lamotrigine GH [GQ] | [a] LAMOTRIGINE-WGR [WG] |
| | | | | | | [a] Logem [AL] | [a] Reedos 100 [ZS] |
| | | | | | | [a] Sandoz Lamotrigine [HX] | |
| | | | [B]6.90 | 37.62 | 25.00 | [a] Lamictal [AS] | |

**lamotrigine 200 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13843N | | | | | | | |
| NP | 2 | 5 | 0.00 | *41.86 | 25.00 | [a] APX-Lamotrigine [TY] | [a] LAMITAN [RF] |
| | | | | | | [a] Lamotrigine GH [GQ] | [a] LAMOTRIGINE-WGR [WG] |
| | | | | | | [a] Logem [AL] | [a] Reedos 200 [ZS] |
| | | | | | | [a] Sandoz Lamotrigine [HX] | |
| | | | [B]6.92 | 48.78 | 25.00 | [a] Lamictal [AS] | |

## LAMOTRIGINE

**Restricted benefit**

***18507***

Bipolar disorder

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**lamotrigine 5 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15341K | | | | | | |
| NP | 1 | 5 | 0.00 | 19.39 | 20.93 | Lamictal [AS] |

**lamotrigine 25 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 15338G | | | | | | | |
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] Lamotrigine GH [GQ] | [a] Sandoz Lamotrigine [HX] |
| | | | [B]4.08 | 22.68 | 20.14 | [a] Lamictal [AS] | |

**lamotrigine 50 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 15349W | | | | | | | |
| NP | 1 | 5 | 0.00 | 19.31 | 20.85 | [a] Lamotrigine GH [GQ] | [a] Sandoz Lamotrigine [HX] |
| | | | [B]3.44 | 22.75 | 20.85 | [a] Lamictal [AS] | |

**lamotrigine 100 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 15343M | | | | | | | |
| NP | 1 | 5 | 0.00 | 22.54 | 24.08 | [a] Lamotrigine GH [GQ] | [a] Sandoz Lamotrigine [HX] |
| | | | [B]3.45 | 25.99 | 24.08 | [a] Lamictal [AS] | |

**lamotrigine 200 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 15350X | | | | | | | |
| NP | 1 | 5 | 0.00 | 28.11 | 25.00 | [a] Lamotrigine GH [GQ] | [a] Sandoz Lamotrigine [HX] |
| | | | [B]3.46 | 31.57 | 25.00 | [a] Lamictal [AS] | |

## LAMOTRIGINE

**Restricted benefit**

***18508***

Bipolar disorder

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**lamotrigine 5 mg tablet, 56**

| 15339H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.42 | 25.00 | Lamictal [AS] |

**lamotrigine 25 mg tablet, 56**

| 15346Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] Lamotrigine GH [GQ] | [a] Sandoz Lamotrigine [HX] |
| | | | [B]8.16 | *31.00 | 24.38 | [a] Lamictal [AS] | |

**lamotrigine 50 mg tablet, 56**

| 15342L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *24.26 | 25.00 | [a] Lamotrigine GH [GQ] | [a] Sandoz Lamotrigine [HX] |
| | | | [B]6.88 | *31.14 | 25.00 | [a] Lamictal [AS] | |

**lamotrigine 100 mg tablet, 56**

| 15340J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *30.72 | 25.00 | [a] Lamotrigine GH [GQ] | [a] Sandoz Lamotrigine [HX] |
| | | | [B]6.90 | *37.62 | 25.00 | [a] Lamictal [AS] | |

**lamotrigine 200 mg tablet, 56**

| 15351Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *41.86 | 25.00 | [a] Lamotrigine GH [GQ] | [a] Sandoz Lamotrigine [HX] |
| | | | [B]6.92 | *48.78 | 25.00 | [a] Lamictal [AS] | |

## LEVETIRACETAM

**Restricted benefit**

***17460***

Epileptic seizures

**Clinical criteria:**

- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**levetiracetam 250 mg tablet, 60**

| 8654L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.85 | 23.39 | [a] APO-Levetiracetam [TX] | [a] Keppra [UC] |
| | | | | | | [a] Levactam [ZS] | [a] Levetiracetam GH [GQ] |
| | | | | | | [a] Levetiracetam SZ [SZ] | [a] Levetiracetam Viatris [MQ] |
| | | | | | | [a] LEVETIRACETAM-WGR [WG] | [a] Levi 250 [RW] |

**levetiracetam 500 mg tablet, 60**

| 8655M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 26.83 | 25.00 | [a] APO-Levetiracetam [TX] | [a] Keppra [UC] |
| | | | | | | [a] Levactam [ZS] | [a] Levetiracetam GH [GQ] |
| | | | | | | [a] Levetiracetam SZ [SZ] | [a] Levetiracetam Viatris [MQ] |
| | | | | | | [a] LEVETIRACETAM-WGR [WG] | [a] Levi 500 [RW] |

**levetiracetam 1 g tablet, 60**

| 8656N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 41.23 | 25.00 | [a] APO-Levetiracetam [TX] | [a] Keppra [UC] |
| | | | | | | [a] Levactam [ZS] | [a] Levetiracetam GH [GQ] |
| | | | | | | [a] Levetiracetam SZ [SZ] | [a] Levetiracetam Viatris [MQ] |
| | | | | | | [a] LEVETIRACETAM-WGR [WG] | [a] Levi 1000 [RW] |

## LEVETIRACETAM

**Restricted benefit**

***17563***

Epileptic seizures

**Clinical criteria:**

- Patient must be unable to take a solid dose form of levetiracetam, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**levetiracetam 100 mg/mL oral liquid, 300 mL**

| 9169N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 77.07 | 25.00 | [a] APO-Levetiracetam [TX] | [a] Keppra [UC] |
| | | | | | | [a] Kerron [ZS] | [a] Levetiracetam-AFT [AE] |
| | | | | | | [a] Levetiracetam GH [GQ] | |

## LEVETIRACETAM

**Restricted benefit**

***17543***

Epileptic seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**levetiracetam 250 mg tablet, 60**

| 13992K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *29.34 | 25.00 | [a] APO-Levetiracetam [TX] | [a] Keppra [UC] |
| | | | | | | [a] Levactam [ZS] | [a] Levetiracetam GH [GQ] |
| | | | | | | [a] Levetiracetam SZ [SZ] | [a] Levetiracetam Viatris [MQ] |
| | | | | | | [a] LEVETIRACETAM-WGR [WG] | [a] Levi 250 [RW] |

**levetiracetam 500 mg tablet, 60**

| 14034P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *39.30 | 25.00 | [a] APO-Levetiracetam [TX] | [a] Keppra [UC] |
| | | | | | | [a] Levactam [ZS] | [a] Levetiracetam GH [GQ] |
| | | | | | | [a] Levetiracetam SZ [SZ] | [a] Levetiracetam Viatris [MQ] |
| | | | | | | [a] LEVETIRACETAM-WGR [WG] | [a] Levi 500 [RW] |

**levetiracetam 1 g tablet, 60**

| 13937M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *68.10 | 25.00 | [a] APO-Levetiracetam [TX] | [a] Keppra [UC] |
| | | | | | | [a] Levactam [ZS] | [a] Levetiracetam GH [GQ] |
| | | | | | | [a] Levetiracetam SZ [SZ] | [a] Levetiracetam Viatris [MQ] |
| | | | | | | [a] LEVETIRACETAM-WGR [WG] | [a] Levi 1000 [RW] |

## LEVETIRACETAM

**Restricted benefit**

***17564***

Epileptic seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be unable to take a solid dose form of levetiracetam, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**levetiracetam 100 mg/mL oral liquid, 300 mL**

| 13993L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *141.06 | 25.00 | [a] APO-Levetiracetam [TX] | [a] Keppra [UC] |
| | | | | | | [a] Kerron [ZS] | [a] Levetiracetam-AFT [AE] |
| | | | | | | [a] Levetiracetam GH [GQ] | |

## PERAMPANEL

**Authority Required (STREAMLINED)**

***17517***

Intractable focal onset seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug.

**perampanel 4 mg tablet, 28**

| 10162W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 145.38 | 25.00 | Fycompa [EI] |

**perampanel 6 mg tablet, 28**

| 10163X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 213.39 | 25.00 | Fycompa [EI] |

**perampanel 8 mg tablet, 28**

| 10160R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 281.37 | 25.00 | Fycompa [EI] |

**perampanel 10 mg tablet, 28**

| 10151G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 281.37 | 25.00 | Fycompa [EI] |

**perampanel 12 mg tablet, 28**

| 10159Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 281.37 | 25.00 | Fycompa [EI] |

## PERAMPANEL

**Authority Required (STREAMLINED)**

***17577***

Intractable focal onset seizures

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with two or more antiseizure medications which include one second-line adjunctive agent, **AND**
- The condition must have failed to be controlled satisfactorily by other antiseizure medications, which include at least one first-line antiseizure agent and at least two second-line adjunctive antiseizure agents.

**Treatment criteria:**

- Must be treated by a neurologist.

**perampanel 2 mg tablet, 7**

| 10157N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 1 | 0.00 | *46.74 | 25.00 | Fycompa [EI] |

## PERAMPANEL

**Authority Required (STREAMLINED)**

***17481***

Intractable focal onset seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously been issued with an authority prescription for this drug.

**perampanel 4 mg tablet, 28**

| 13948D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *281.40 | 25.00 | Fycompa [EI] |

**perampanel 6 mg tablet, 28**

| 14010J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *417.42 | 25.00 | Fycompa [EI] |

**perampanel 8 mg tablet, 28**

| 13970G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *553.38 | 25.00 | Fycompa [EI] |

**perampanel 10 mg tablet, 28**

| 13914H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *553.38 | 25.00 | Fycompa [EI] |

**perampanel 12 mg tablet, 28**

| 13865R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *553.38 | 25.00 | Fycompa [EI] |

## PERAMPANEL

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required (STREAMLINED)**

***17570***

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least two antiseizure medications, **AND**
- The treatment must be in combination with at least one PBS-subsidised antiseizure medication.

**Population criteria:**

- Patient must be aged 12 years or older.

**perampanel 2 mg tablet, 7**

| 11436X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 1 | 0.00 | *46.74 | 25.00 | Fycompa [EI] |

## PERAMPANEL

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***7789***

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must be aged 12 years or older.

**perampanel 4 mg tablet, 28**

| 11418Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 145.38 | 25.00 | Fycompa [EI] |

**perampanel 6 mg tablet, 28**

| 11407J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 213.39 | 25.00 | Fycompa [EI] |

**perampanel 8 mg tablet, 28**

| 11429M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 281.37 | 25.00 | Fycompa [EI] |

**perampanel 10 mg tablet, 28**

| 11428L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 281.37 | 25.00 | Fycompa [EI] |

**perampanel 12 mg tablet, 28**

| 11409L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 281.37 | 25.00 | Fycompa [EI] |

## PERAMPANEL

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**
***14847***
Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures
Treatment Phase: Continuing treatment
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Population criteria:**

- Patient must be aged 12 years or older.

### perampanel 4 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13864Q NP | 2 | 5 | 0.00 | *281.40 | 25.00 | Fycompa [EI] |

### perampanel 6 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14046G NP | 2 | 5 | 0.00 | *417.42 | 25.00 | Fycompa [EI] |

### perampanel 8 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13915J NP | 2 | 5 | 0.00 | *553.38 | 25.00 | Fycompa [EI] |

### perampanel 10 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13971H NP | 2 | 5 | 0.00 | *553.38 | 25.00 | Fycompa [EI] |

### perampanel 12 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14012L NP | 2 | 5 | 0.00 | *553.38 | 25.00 | Fycompa [EI] |

## STIRIPENTOL

**Authority Required (STREAMLINED)**
***17456***
Severe myoclonic epilepsy in infancy (Dravet syndrome)
**Clinical criteria:**

- Patient must have (as an initiating patient)/have had (as a continuing patient), generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other antiseizure medications, **AND**
- The treatment must be as adjunctive therapy to at least two other antiseizure medications.

**Treatment criteria:**

- Must be treated by a neurologist if treatment is being initiated; **OR**
- Must be treated by a neurologist if treatment is being continued or re-initiated; **OR**
- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; **OR**
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

### stiripentol 250 mg capsule, 60

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12103B | 2 | 3 | 0.00 | *651.12 | 25.00 | Diacomit [EU] |

### stiripentol 250 mg powder for oral liquid, 60 sachets

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12106E | 2 | 3 | 0.00 | *651.12 | 25.00 | Diacomit [EU] |

### stiripentol 500 mg powder for oral liquid, 60 sachets

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12088F | 2 | 3 | 0.00 | *1,292.88 | 25.00 | Diacomit [EU] |

### stiripentol 500 mg capsule, 60

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12107F | 2 | 3 | 0.00 | *1,292.88 | 25.00 | Diacomit [EU] |

## SULTHIAME

**Restricted benefit**
***16524***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**sulthiame 50 mg tablet, 200**

| 2099L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 68.84 | 25.00 | Ospolot [FF] |

**sulthiame 200 mg tablet, 200**

| 2100M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 159.58 | 25.00 | Ospolot [FF] |

## SULTHIAME

**Restricted benefit**

***16493***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**sulthiame 50 mg tablet, 200**

| 13916K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *123.76 | 25.00 | Ospolot [FF] |

**sulthiame 200 mg tablet, 200**

| 14016Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *309.80 | 25.00 | Ospolot [FF] |

## TOPIRAMATE

**Authority Required (STREAMLINED)**

***17487***

Seizures

**Clinical criteria:**

- Patient must have focal onset seizures; **OR**
- Patient must have primary generalised tonic-clonic seizures; **OR**
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**topiramate 200 mg tablet, 60**

| 8166T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 28.87 | 25.00 | [a] APO-Topiramate [TX] | [a] Epiramax 200 [RW] |
| | | | | | | [a] RBX Topiramate [RA] | [a] Tamate [AF] |
| | | | | | | [a] Topiramate Sandoz [SZ] | [a] TOPIRAMATE-WGR [WG] |

## TOPIRAMATE

**Authority Required (STREAMLINED)**

***17488***

Seizures

**Clinical criteria:**

- Patient must have focal onset seizures; **OR**
- Patient must have primary generalised tonic-clonic seizures; **OR**
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication, **AND**
- Patient must be unable to take a solid dose form of topiramate.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**topiramate 15 mg capsule, 60**

| 8371N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 25.33 | 25.00 | Topamax Sprinkle [JC] |

**topiramate 25 mg capsule, 60**

| 8372P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 23.39 | 24.93 | Topamax Sprinkle [JC] |

**topiramate 50 mg capsule, 60**

| 8520K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 29.42 | 25.00 | Topamax Sprinkle [JC] |

## TOPIRAMATE

**Authority Required (STREAMLINED)**

***17525***

Seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have focal onset seizures; **OR**
- Patient must have primary generalised tonic-clonic seizures; **OR**
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication, **AND**
- Patient must be unable to take a solid dose form of topiramate.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**topiramate 15 mg capsule, 60**

| 14063E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *36.30 | 25.00 | Topamax Sprinkle [JC] |

**topiramate 25 mg capsule, 60**

| 13905W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *32.42 | 25.00 | Topamax Sprinkle [JC] |

**topiramate 50 mg capsule, 60**

| 13878K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *44.48 | 25.00 | Topamax Sprinkle [JC] |

## TOPIRAMATE

**Authority Required (STREAMLINED)**

***17562***

Seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have focal onset seizures; **OR**
- Patient must have primary generalised tonic-clonic seizures; **OR**
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**topiramate 200 mg tablet, 60**

| 14009H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *43.38 | 25.00 | [a] APO-Topiramate [TX] | [a] Epiramax 200 [RW] |
| | | | | | | [a] RBX Topiramate [RA] | [a] Tamate [AF] |
| | | | | | | [a] Topiramate Sandoz [SZ] | [a] TOPIRAMATE-WGR [WG] |

## TOPIRAMATE

**Authority Required (STREAMLINED)**

***17487***

Seizures

**Clinical criteria:**

- Patient must have focal onset seizures; **OR**
- Patient must have primary generalised tonic-clonic seizures; **OR**
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***5325***

Migraine

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; **OR**
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; **OR**
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

**topiramate 25 mg tablet, 60**

| 8163P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Topiramate [TX] | [a] Epiramax 25 [RW] |
| | | | | | | [a] RBX Topiramate [RA] | [a] Tamate [AF] |
| | | | | | | [a] Topiramate Sandoz [SZ] | [a] TOPIRAMATE-WGR [WG] |

**topiramate 50 mg tablet, 60**

| 8164Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.86 | 21.40 | [a] APO-Topiramate [TX] | [a] Epiramax 50 [RW] |
| | | | | | | [a] RBX Topiramate [RA] | [a] Tamate [AF] |
| | | | | | | [a] Topiramate Sandoz [SZ] | [a] TOPIRAMATE-WGR [WG] |

**topiramate 100 mg tablet, 60**

| 8165R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 22.99 | 24.53 | [a] APO-Topiramate [TX] | [a] Epiramax 100 [RW] |
| | | | | | | [a] RBX Topiramate [RA] | [a] Tamate [AF] |
| | | | | | | [a] Topiramate Sandoz [SZ] | [a] TOPIRAMATE-WGR [WG] |

## TOPIRAMATE

**Authority Required (STREAMLINED)**

***17562***

Seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have focal onset seizures; **OR**
- Patient must have primary generalised tonic-clonic seizures; **OR**
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required (STREAMLINED)**

***14901***

Migraine

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; **OR**
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; **OR**
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

**topiramate 25 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13969F | | | | | | | |
| NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Topiramate [TX] | [a] Epiramax 25 [RW] |
| | | | | | | [a] RBX Topiramate [RA] | [a] Tamate [AF] |
| | | | | | | [a] Topiramate Sandoz [SZ] | [a] TOPIRAMATE-WGR [WG] |

**topiramate 50 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 13913G | | | | | | | |
| NP | 2 | 5 | 0.00 | *25.36 | 25.00 | [a] APO-Topiramate [TX] | [a] Epiramax 50 [RW] |
| | | | | | | [a] RBX Topiramate [RA] | [a] Tamate [AF] |
| | | | | | | [a] Topiramate Sandoz [SZ] | [a] TOPIRAMATE-WGR [WG] |

**topiramate 100 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14008G | | | | | | | |
| NP | 2 | 5 | 0.00 | *31.62 | 25.00 | [a] APO-Topiramate [TX] | [a] Epiramax 100 [RW] |
| | | | | | | [a] RBX Topiramate [RA] | [a] Tamate [AF] |
| | | | | | | [a] Topiramate Sandoz [SZ] | [a] TOPIRAMATE-WGR [WG] |

## ZONISAMIDE

**Authority Required (STREAMLINED)**

***17445***

Focal onset seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**zonisamide 25 mg capsule, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9388D | | | | | | |
| NP | 1 | 5 | 0.00 | 25.22 | 25.00 | Zonegran [GH] |

**zonisamide 50 mg capsule, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9389E | | | | | | |
| NP | 1 | 5 | 0.00 | 32.47 | 25.00 | Zonegran [GH] |

**zonisamide 100 mg capsule, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9390F | | | | | | |
| NP | 2 | 5 | 0.00 | *74.70 | 25.00 | Zonegran [GH] |

## ZONISAMIDE

**Authority Required (STREAMLINED)**

***17444***

Focal onset seizures

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have failed to be controlled satisfactorily by at least one other antiseizure medication.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**zonisamide 25 mg capsule, 56**

| 13853D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *36.08 | 25.00 | Zonegran [GH] |

**zonisamide 50 mg capsule, 56**

| 13988F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *50.58 | 25.00 | Zonegran [GH] |

**zonisamide 100 mg capsule, 56**

| 13854E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *136.08 | 25.00 | Zonegran [GH] |

## ANTI-PARKINSON DRUGS

### ANTICHOLINERGIC AGENTS

#### *Tertiary amines*

### TRIHEXYPHENIDYL

**trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200**

| 1109J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 19.40 | 20.94 | Artane [RW] |

**trihexyphenidyl (benzhexol) hydrochloride 5 mg tablet, 200**

| 1110K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 23.01 | 24.55 | Artane [RW] |

#### *Ethers of tropine or tropine derivatives*

### BENZATROPINE

**benzatropine mesilate 2 mg tablet, 60**

| 2362H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 19.05 | 20.59 | Benztrop [FF] |

**benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials**

| 11249C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 116.21 | 25.00 | Benzatropine Injection [FF] |

**benzatropine mesilate 2 mg/2 mL injection, 5 x 2 mL vials**

| 11255J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 116.21 | 25.00 | Benzatropine Injection [FF] |

### DOPAMINERGIC AGENTS

#### *Dopa and dopa derivatives*

### FOSLEVODOPA + FOSCARBIDOPA

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16951***

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- The treatment must have been commenced by a specialist physician; **OR**
- The treatment must have been commenced by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease, **AND**
- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must require continuous administration of foslevodopa without an overnight break; **OR**
- Patient must require a total daily dose of more than 2,400 mg of foslevodopa.

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**foslevodopa 2.4 g/10 mL + foscarbidopa 120 mg/10 mL injection, 7 x 10 mL vials**

| 14876Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *10,445.80 | 25.00 | Vyalev [VE] |

## FOSLEVODOPA + FOSCARBIDOPA

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16853***

Advanced Parkinson disease

**Treatment criteria:**

- Must be treated by a specialist physician; **OR**
- Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease.

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must require continuous administration of foslevodopa without an overnight break; **OR**
- Patient must require a total daily dose of more than 2,400 mg of foslevodopa.

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

### foslevodopa 2.4 g/10 mL + foscarbidopa 120 mg/10 mL injection, 7 x 10 mL vials

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14886L | 8 | 5 | 0.00 | *10,445.80 | 25.00 | Vyalev [VE] |

## FOSLEVODOPA + FOSCARBIDOPA

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16812***

Advanced Parkinson disease

**Treatment criteria:**

- Must be treated by a specialist physician; **OR**
- Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease.

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy.

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

### foslevodopa 2.4 g/10 mL + foscarbidopa 120 mg/10 mL injection, 7 x 10 mL vials

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14887M | 4 | 5 | 0.00 | *5,277.56 | 25.00 | Vyalev [VE] |

## FOSLEVODOPA + FOSCARBIDOPA

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***16882***

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- The treatment must have been commenced by a specialist physician; **OR**
- The treatment must have been commenced by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease, **AND**
- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy.

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

### foslevodopa 2.4 g/10 mL + foscarbidopa 120 mg/10 mL injection, 7 x 10 mL vials

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14896B | | | | | | |
| NP | 4 | 5 | 0.00 | *5,277.56 | 25.00 | Vyalev [VE] |

## LEVODOPA + BENSERAZIDE

**Restricted benefit**

***16524***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**levodopa 50 mg + benserazide 12.5 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2227F | | | | | | |
| NP | 1 | 5 | 0.00 | 25.72 | 25.00 | Madopar 62.5 [RO] |

**levodopa 50 mg + benserazide 12.5 mg dispersible tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8218M | | | | | | |
| NP | 1 | 5 | 0.00 | 25.72 | 25.00 | Madopar Rapid 62.5 [RO] |

**levodopa 100 mg + benserazide 25 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2225D | | | | | | |
| NP | 1 | 5 | 0.00 | 29.95 | 25.00 | Madopar 125 [RO] |

**levodopa 100 mg + benserazide 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2229H | | | | | | |
| NP | 1 | 5 | 0.00 | 29.95 | 25.00 | Madopar 125 [RO] |

**levodopa 100 mg + benserazide 25 mg modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2231K | | | | | | |
| NP | 1 | 5 | 0.00 | 33.41 | 25.00 | Madopar HBS [RO] |

**levodopa 100 mg + benserazide 25 mg dispersible tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8219N | | | | | | |
| NP | 1 | 5 | 0.00 | 35.51 | 25.00 | Madopar Rapid 125 [RO] |

**levodopa 200 mg + benserazide 50 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2226E | | | | | | |
| NP | 1 | 5 | 0.00 | 39.61 | 25.00 | Madopar [RO] |

**levodopa 200 mg + benserazide 50 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2228G | | | | | | |
| NP | 1 | 5 | 0.00 | 39.61 | 25.00 | Madopar [RO] |

## LEVODOPA + BENSERAZIDE

**Restricted benefit**

***16493***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**levodopa 50 mg + benserazide 12.5 mg dispersible tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14356N | | | | | | |
| NP | 2 | 5 | 0.00 | *37.08 | 25.00 | Madopar Rapid 62.5 [RO] |

**levodopa 50 mg + benserazide 12.5 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14388G | | | | | | |
| NP | 2 | 5 | 0.00 | *37.08 | 25.00 | Madopar 62.5 [RO] |

**levodopa 100 mg + benserazide 25 mg capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14387F | | | | | | |
| NP | 2 | 5 | 0.00 | *45.54 | 25.00 | Madopar 125 [RO] |

**levodopa 100 mg + benserazide 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14455T | | | | | | |
| NP | 2 | 5 | 0.00 | *45.54 | 25.00 | Madopar 125 [RO] |

**levodopa 100 mg + benserazide 25 mg modified release capsule, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14525L | | | | | | |
| NP | 2 | 5 | 0.00 | *52.46 | 25.00 | Madopar HBS [RO] |

**levodopa 100 mg + benserazide 25 mg dispersible tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14552X | | | | | | |
| NP | 2 | 5 | 0.00 | *56.66 | 25.00 | Madopar Rapid 125 [RO] |

**levodopa 200 mg + benserazide 50 mg tablet, 100**

| 14428J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *64.86 | 25.00 | Madopar [RO] |

**levodopa 200 mg + benserazide 50 mg capsule, 100**

| 14551W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *64.86 | 25.00 | Madopar [RO] |

## LEVODOPA + CARBIDOPA

**Restricted benefit**

***16524***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**levodopa 100 mg + carbidopa 25 mg tablet, 100**

| 1242J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 32.77 | 25.00 | [a] APO-Levodopa/Carbidopa [TX] | [a] Kinson [AF] |
| | | | | | | [a] ORIDOPA 100/25 [OX] | [a] SINADOPA 100/25 [RW] |
| | | | | | | [a] Sinemet 100/25 [AL] | |

**levodopa 250 mg + carbidopa 25 mg tablet, 100**

| 1245M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 37.07 | 25.00 | [a] APO-Levodopa/Carbidopa [TX] | [a] SINADOPA 250/25 [RW] |
| | | | | | | [a] Sinemet [AL] | |

## LEVODOPA + CARBIDOPA

**Restricted benefit**

***16688***

Parkinson disease

**Clinical criteria:**

- The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**levodopa 200 mg + carbidopa 50 mg modified release tablet, 100**

| 1255C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 68.54 | 25.00 | Sinemet CR [AL] |

## LEVODOPA + CARBIDOPA

**Restricted benefit**

***16624***

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**levodopa 200 mg + carbidopa 50 mg modified release tablet, 100**

| 14322T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *123.14 | 25.00 | Sinemet CR [AL] |

## LEVODOPA + CARBIDOPA

**Restricted benefit**

***16493***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### levodopa 100 mg + carbidopa 25 mg tablet, 100

| 14427H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *51.18 | 25.00 | [a] APO-Levodopa/Carbidopa [TX] | [a] Kinson [AF] |
| | | | | | | [a] ORIDOPA 100/25 [OX] | [a] SINADOPA 100/25 [RW] |
| | | | | | | [a] Sinemet 100/25 [AL] | |

### levodopa 250 mg + carbidopa 25 mg tablet, 100

| 14454R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *59.78 | 25.00 | [a] APO-Levodopa/Carbidopa [TX] | [a] SINADOPA 250/25 [RW] |
| | | | | | | [a] Sinemet [AL] | |

## LEVODOPA + CARBIDOPA

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***10386***

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must have been commenced on treatment in a hospital-based movement disorder clinic, **AND**
- Patient must require continuous administration of levodopa without an overnight break; **OR**
- Patient must require a total daily dose of more than 2000 mg of levodopa.

### levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

| 8970D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *12,060.12 | 25.00 | Duodopa [VE] |

## LEVODOPA + CARBIDOPA

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.
**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***10197***

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must have been commenced on treatment in a hospital-based movement disorder clinic.

### levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

| 11919H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *6,084.72 | 25.00 | Duodopa [VE] |

## LEVODOPA + CARBIDOPA + ENTACAPONE

**Restricted benefit**

***16592***

Parkinson disease

**Clinical criteria:**

- Patient must be being treated with levodopa decarboxylase inhibitor combinations, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

***16591***

Parkinson disease

**Clinical criteria:**

- Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**levodopa 50 mg + carbidopa 12.5 mg + entacapone 200 mg tablet, 100**

| 8797B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *97.72 | 25.00 | [a] Carlevent [TX] | [a] L.C.E. Sandoz [HX] |
| | | | | | | [a] Lecteva [TB] | [a] Stalevo 50/12.5/200mg [SZ] |

**levodopa 75 mg + carbidopa 18.75 mg + entacapone 200 mg tablet, 100**

| 9344T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *101.56 | 25.00 | [a] Carlevent [TX] | [a] L.C.E. Sandoz [HX] |
| | | | | | | [a] Lecteva [TB] | [a] Stalevo 75/18.75/200mg [SZ] |

**levodopa 100 mg + carbidopa 25 mg + entacapone 200 mg tablet, 100**

| 8798C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *106.44 | 25.00 | [a] Carlevent [TX] | [a] L.C.E. Sandoz [HX] |
| | | | | | | [a] Lecteva [TB] | [a] Stalevo 100/25/200mg [SZ] |

**levodopa 125 mg + carbidopa 31.25 mg + entacapone 200 mg tablet, 100**

| 9345W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *109.92 | 25.00 | [a] Carlevent [TX] | [a] L.C.E. Sandoz [HX] |
| | | | | | | [a] Lecteva [TB] | [a] Stalevo 125/31.25/200mg [SZ] |

**levodopa 150 mg + carbidopa 37.5 mg + entacapone 200 mg tablet, 100**

| 8799D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *115.20 | 25.00 | [a] Carlevent [TX] | [a] L.C.E. Sandoz [HX] |
| | | | | | | [a] Lecteva [TB] | [a] Stalevo 150/37.5/200mg [SZ] |

**levodopa 200 mg + carbidopa 50 mg + entacapone 200 mg tablet, 100**

| 9292C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *123.60 | 25.00 | [a] Carlevent [TX] | [a] L.C.E. Sandoz [HX] |
| | | | | | | [a] Lecteva [TB] | [a] Stalevo 200/50/200mg [SZ] |

## LEVODOPA + CARBIDOPA + ENTACAPONE

**Restricted benefit**

***16534***

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be being treated with levodopa decarboxylase inhibitor combinations, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Restricted benefit**

***16533***

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**levodopa 50 mg + carbidopa 12.5 mg + entacapone 200 mg tablet, 100**

| 14456W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 4 | 0.00 | *184.40 | 25.00 | [a] Carlevent [TX] | [a] L.C.E. Sandoz [HX] |
| | | | | | | [a] Lecteva [TB] | [a] Stalevo 50/12.5/200mg [SZ] |

**levodopa 75 mg + carbidopa 18.75 mg + entacapone 200 mg tablet, 100**

| 14498C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 4 | 0.00 | *192.48 | 25.00 | [a] Carlevent [TX] | [a] L.C.E. Sandoz [HX] |
| | | | | | | [a] Lecteva [TB] | [a] Stalevo 75/18.75/200mg [SZ] |

**levodopa 100 mg + carbidopa 25 mg + entacapone 200 mg tablet, 100**

| 14554B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 4 | 0.00 | *202.72 | 25.00 | [a] Carlevent [TX] | [a] L.C.E. Sandoz [HX] |
| | | | | | | [a] Lecteva [TB] | [a] Stalevo 100/25/200mg [SZ] |

**levodopa 125 mg + carbidopa 31.25 mg + entacapone 200 mg tablet, 100**

| 14527N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 4 | 0.00 | *210.04 | 25.00 | [a] Carlevent [TX] | [a] L.C.E. Sandoz [HX] |
| | | | | | | [a] Lecteva [TB] | [a] Stalevo 125/31.25/200mg [SZ] |

**levodopa 150 mg + carbidopa 37.5 mg + entacapone 200 mg tablet, 100**

| 14357P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 4 | 0.00 | *221.04 | 25.00 | [a] Carlevent [TX] | [a] L.C.E. Sandoz [HX] |
| | | | | | | [a] Lecteva [TB] | [a] Stalevo 150/37.5/200mg [SZ] |

**levodopa 200 mg + carbidopa 50 mg + entacapone 200 mg tablet, 100**

| 14457X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 4 | 0.00 | *237.84 | 25.00 | [a] Carlevent [TX] | [a] L.C.E. Sandoz [HX] |
| | | | | | | [a] Lecteva [TB] | [a] Stalevo 200/50/200mg [SZ] |

## *Adamantane derivatives*

### AMANTADINE

**Restricted benefit**

***16670***

Parkinson disease

**Clinical criteria:**

- The condition must not be drug induced.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**amantadine hydrochloride 100 mg capsule, 100**

| 3016R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 37.56 | 25.00 | [a] AMANTAMED [DZ] | [a] Symmetrel 100 [NV] |

### AMANTADINE

**Restricted benefit**

***16621***

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be drug induced.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**amantadine hydrochloride 100 mg capsule, 100**

| 14486K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *60.76 | 25.00 | [a] AMANTAMED [DZ] | [a] Symmetrel 100 [NV] |

## *Dopamine agonists*

## APOMORPHINE

**Authority Required (STREAMLINED)**

***10844***

Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

**apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules**

| 12306Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 36 | 5 | 0.00 | *6,398.16 | 25.00 | Movapo [TD] |

**apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes**

| 12319J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 36 | 5 | 0.00 | *8,471.40 | 25.00 | Movapo PFS [TD] |

**apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials**

| 12142C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 18 | 5 | 0.00 | *7,855.98 | 25.00 | Apomine Solution for Infusion [IT] |

**Apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL cartridges**

| 15118Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 18 | 5 | 0.00 | *7,855.98 | 25.00 | MOVAPO POD [TD] |

## APOMORPHINE

**Authority Required (STREAMLINED)**

***15542***

Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

**apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules**

| 14407G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 72 | 5 | 0.00 | *12,687.00 | 25.00 | Movapo [TD] |

**apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes**

| 14377Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 72 | 5 | 0.00 | *16,833.48 | 25.00 | Movapo PFS [TD] |

**apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials**

| 14375N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 36 | 5 | 0.00 | *15,602.64 | 25.00 | Apomine Solution for Infusion [IT] |

**Apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL cartridges**

| 15121W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 36 | 5 | 0.00 | *15,602.64 | 25.00 | MOVAPO POD [TD] |

## APOMORPHINE

**Note** Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required (STREAMLINED)**

***10844***

Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

**apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges**

| 12133N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 20 | 5 | 0.00 | *2,808.64 | 25.00 | [a] Apomine Intermittent [IT] |

**apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices**

| 12137T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 20 | 5 | 0.00 | *2,808.64 | 25.00 | [a] Movapo Pen [TD] |

## APOMORPHINE

**Note** Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority Required (STREAMLINED)**

***15542***

Parkinson disease

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

**apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges**

| 14309D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 40 | 5 | 0.00 | *5,507.64 | 25.00 | [a] Apomine Intermittent [IT] |

**apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices**

| 14485J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 40 | 5 | 0.00 | *5,507.64 | 25.00 | [a] Movapo Pen [TD] |

## BROMOCRIPTINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***6717***

Acromegaly

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***6718***

Parkinson disease

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***6787***

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom surgery is not indicated.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***6706***

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had surgery for this condition with incomplete resolution.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***6707***

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must be one in whom radiotherapy is not indicated.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***6719***

Pathological hyperprolactinaemia

**Clinical criteria:**

- Patient must have had radiotherapy for this condition with incomplete resolution.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

### bromocriptine 2.5 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1443Y | 2 | 5 | 0.00 | *33.06 | 25.00 | Parlodel [SZ] |

## BROMOCRIPTINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***14914***

Acromegaly

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***15028***

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***15043***

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom surgery is not indicated.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***14981***

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had surgery for this condition with incomplete resolution.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***15044***

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be one in whom radiotherapy is not indicated.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***15017***

Pathological hyperprolactinaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have had radiotherapy for this condition with incomplete resolution.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**bromocriptine 2.5 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13979R | 4 | 5 | 0.00 | *51.76 | 25.00 | Parlodel [SZ] |

## CABERGOLINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***16536***

Parkinson disease

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**cabergoline 1 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8393R NP | 1 | 5 | 0.00 | 36.93 | 25.00 | Cabaser [PF] |

**cabergoline 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8394T NP | 1 | 5 | 0.00 | 49.06 | 25.00 | Cabaser [PF] |

## CABERGOLINE

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***16540***

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**cabergoline 1 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14516B NP | 2 | 5 | 0.00 | *59.50 | 25.00 | Cabaser [PF] |

**cabergoline 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14543K NP | 2 | 5 | 0.00 | *83.76 | 25.00 | Cabaser [PF] |

## PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**

***5411***

Primary severe restless legs syndrome

**Clinical criteria:**

- Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome, **AND**
- Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and

(b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and

(c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and

(d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.
**Note** This drug is not PBS-subsidised for Restless Legs Syndrome secondary to other causes
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**pramipexole dihydrochloride monohydrate 125 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9393J NP | 1 | 2 | 0.00 | 17.64 | 19.18 | [a] APO-Pramipexole [TX] | [a] Simipex 0.125 [RW] |
| | | | | | | [a] Simpral [AF] | |
| | | | [B]3.54 | 21.18 | 19.18 | [a] Sifrol [BY] | |

**pramipexole dihydrochloride monohydrate 250 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9394K NP | 1 | 2 | 0.00 | 28.70 | 25.00 | [a] APO-Pramipexole [TX] | [a] Simipex 0.25 [RW] |
| | | | | | | [a] Simpral [AF] | |
| | | | [B]3.65 | 32.35 | 25.00 | [a] Sifrol [BY] | |

## PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.
**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**
***16536***
Parkinson disease
**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**pramipexole dihydrochloride monohydrate 125 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9151P NP | 1 | 0 | 0.00 | 17.64 | 19.18 | [a] APO-Pramipexole [TX] | [a] Simipex 0.125 [RW] |
| | | | | | | [a] Simpral [AF] | |
| | | | [B]3.54 | 21.18 | 19.18 | [a] Sifrol [BY] | |

**pramipexole dihydrochloride monohydrate 250 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9152Q NP | 1 | 5 | 0.00 | 28.70 | 25.00 | [a] APO-Pramipexole [TX] | [a] Simipex 0.25 [RW] |
| | | | | | | [a] Simpral [AF] | |
| | | | [B]3.65 | 32.35 | 25.00 | [a] Sifrol [BY] | |

**pramipexole dihydrochloride monohydrate 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9153R NP | 1 | 5 | 0.00 | 76.94 | 25.00 | [a] APO-Pramipexole [TX] | [a] Sifrol [BY] |
| | | | | | | [a] Simipex 1 [RW] | [a] Simpral [AF] |

## PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.
**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Restricted benefit**
***16540***
Parkinson disease
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**pramipexole dihydrochloride monohydrate 250 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14329E NP | 2 | 5 | 0.00 | *43.04 | 25.00 | [a] APO-Pramipexole [TX] | [a] Simipex 0.25 [RW] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14329E | | | | | | [a] Simpral [AF] | |
| | | | [B]7.30 | 50.34 | 25.00 | [a] Sifrol [BY] | |

**pramipexole dihydrochloride monohydrate 1 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14532W | | | | | | | |
| NP | 2 | 5 | 0.00 | *140.78 | 25.00 | [a] APO-Pramipexole [TX] | [a] Sifrol [BY] |
| | | | | | | [a] Simipex 1 [RW] | [a] Simpral [AF] |

## PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***16536***

Parkinson disease

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**pramipexole dihydrochloride monohydrate 375 microgram modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3418X | | | | | | | |
| NP | 1 | 5 | 0.00 | 21.89 | 23.43 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

**pramipexole dihydrochloride monohydrate 750 microgram modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3419Y | | | | | | | |
| NP | 1 | 5 | 0.00 | 29.17 | 25.00 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

**pramipexole dihydrochloride monohydrate 1.5 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3420B | | | | | | | |
| NP | 1 | 5 | 0.00 | 43.98 | 25.00 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

**pramipexole dihydrochloride monohydrate 2.25 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5143Q | | | | | | | |
| NP | 1 | 5 | 0.00 | 58.79 | 25.00 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

**pramipexole dihydrochloride monohydrate 3 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3421C | | | | | | | |
| NP | 1 | 5 | 0.00 | 78.99 | 25.00 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

**pramipexole dihydrochloride monohydrate 3.75 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5145T | | | | | | | |
| NP | 1 | 5 | 0.00 | 93.79 | 25.00 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

**pramipexole dihydrochloride monohydrate 4.5 mg modified release tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3422D | | | | | | | |
| NP | 1 | 5 | 0.00 | 111.31 | 25.00 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

## PRAMIPEXOLE

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***16540***

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**pramipexole dihydrochloride monohydrate 375 microgram modified release tablet, 30**

| 14324X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *29.42 | 25.00 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

**pramipexole dihydrochloride monohydrate 750 microgram modified release tablet, 30**

| 14459B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *43.98 | 25.00 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

**pramipexole dihydrochloride monohydrate 1.5 mg modified release tablet, 30**

| 14360T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *73.60 | 25.00 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

**pramipexole dihydrochloride monohydrate 2.25 mg modified release tablet, 30**

| 14556D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *103.22 | 25.00 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

**pramipexole dihydrochloride monohydrate 3 mg modified release tablet, 30**

| 14460C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *145.08 | 25.00 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

**pramipexole dihydrochloride monohydrate 3.75 mg modified release tablet, 30**

| 14461D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *176.16 | 25.00 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

**pramipexole dihydrochloride monohydrate 4.5 mg modified release tablet, 30**

| 14325Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *212.96 | 25.00 | [a] Sifrol ER [BY] | [a] SIMIPEX XR [RW] |

## ROTIGOTINE

**Restricted benefit**

***17323***

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**rotigotine 2 mg/24 hours patch, 28**

| 2385M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 70.74 | 25.00 | Neupro [UC] |

**rotigotine 4 mg/24 hours patch, 28**

| 2384L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 89.53 | 25.00 | Neupro [UC] |

**rotigotine 6 mg/24 hours patch, 28**

| 2410W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 99.66 | 25.00 | Neupro [UC] |

**rotigotine 8 mg/24 hours patch, 28**

| 11140H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 109.20 | 25.00 | Neupro [UC] |

## ROTIGOTINE

**Restricted benefit**

***17278***

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**Treatment criteria:**

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, and (ii) the prescription continues existing therapy with this medicine.

**rotigotine 2 mg/24 hours patch, 28**

| 14327C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *127.76 | 25.00 | Neupro [UC] |

**rotigotine 4 mg/24 hours patch, 28**

| 14326B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *167.22 | 25.00 | Neupro [UC] |

**rotigotine 6 mg/24 hours patch, 28**

| 14431M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *188.50 | 25.00 | Neupro [UC] |

**rotigotine 8 mg/24 hours patch, 28**

| 14359R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *208.52 | 25.00 | Neupro [UC] |

## *Monoamine oxidase B inhibitors*

### RASAGILINE

**Restricted benefit**
***5339***
Parkinson disease

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**rasagiline 1 mg tablet, 30**

| 1952R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 29.56 | 25.00 | [a] Alziras [RW] | [a] Pharmacor Rasagiline [CR] |
| | | | | | | [a] Rasagiline Lupin [HQ] | [a] Rasagiline-Teva [EV] |
| | | | [B]1.94 | 31.50 | 25.00 | [a] Azilect [TB] | |

### RASAGILINE

**Restricted benefit**
***15648***
Parkinson disease
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**rasagiline 1 mg tablet, 30**

| 14458Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *44.76 | 25.00 | [a] Alziras [RW] | [a] Pharmacor Rasagiline [CR] |
| | | | | | | [a] Rasagiline Lupin [HQ] | [a] Rasagiline-Teva [EV] |
| | | | [B]3.88 | 48.64 | 25.00 | [a] Azilect [TB] | |

### SAFINAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**
***8624***
Parkinson disease
**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**safinamide 50 mg tablet, 30**

| 11656L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 50.55 | 25.00 | [a] ARX-Safinamide [XT] | [a] Xadago [IX] |
| | | | | | | [a] XAFIMED [DZ] | |

**safinamide 100 mg tablet, 30**

| 11666B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 86.72 | 25.00 | [a] ARX-Safinamide [XT] | [a] Xadago [IX] |
| | | | | | | [a] XAFIMED [DZ] | |

## SAFINAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***15699***

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

### safinamide 50 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14391K NP | 2 | 5 | 0.00 | *86.74 | 25.00 | [a] ARX-Safinamide [XT]<br>[a] XAFIMED [DZ] | [a] Xadago [IX] |

### safinamide 100 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14528P NP | 2 | 5 | 0.00 | *161.32 | 25.00 | [a] ARX-Safinamide [XT]<br>[a] XAFIMED [DZ] | [a] Xadago [IX] |

## SELEGILINE

**Restricted benefit**

***16541***

Late stage Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### selegiline hydrochloride 5 mg tablet, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1973W NP | 1 | 5 | 0.00 | 53.46 | 25.00 | Eldepryl [OX] |

## SELEGILINE

**Restricted benefit**

***16538***

Late stage Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### selegiline hydrochloride 5 mg tablet, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14430L NP | 2 | 5 | 0.00 | *92.56 | 25.00 | Eldepryl [OX] |

## *Other dopaminergic agents*

## ENTACAPONE

**Restricted benefit**

***16651***

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**entacapone 200 mg tablet, 100**

| 8367J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 4 | 0.00 | *175.00 | 25.00 | Comtan [SZ] |

## ENTACAPONE

**Restricted benefit**

***16690***

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**entacapone 200 mg tablet, 100**

| 14542J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 4 | 0.00 | *340.64 | 25.00 | Comtan [SZ] |

## OPICAPONE

**Restricted benefit**

***16651***

Parkinson disease

**Clinical criteria:**

- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**opicapone 50 mg capsule, 30**

| 13206C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 148.31 | 25.00 | Ongentys [XY] |

## OPICAPONE

**Restricted benefit**

***18125***

Parkinson disease

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**opicapone 50 mg capsule, 30**

| 15268N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *287.26 | 25.00 | Ongentys [XY] |

# PSYCHOLEPTICS

## ANTIPSYCHOTICS

### *Phenothiazines with aliphatic side-chain*

## CHLORPROMAZINE

**Restricted benefit**

***15956***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1201F NP | ‡1 | 5 | 0.00 | 25.47 | 25.00 | Largactil [IX] |

**chlorpromazine hydrochloride 25 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1197B NP | 1 | 5 | 0.00 | 19.18 | 20.72 | Largactil [IX] |

**chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1195X NP | 1 | 0 | 0.00 | 34.72 | 25.00 | Largactil [IX] |

**chlorpromazine hydrochloride 100 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1199D NP | 1 | 5 | 0.00 | 28.99 | 25.00 | Largactil [IX] |

### *Phenothiazines with piperidine structure*

## PERICIAZINE

**Restricted benefit**

***15956***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**periciazine 2.5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3052P NP | 1 | 5 | 0.00 | 19.16 | 20.70 | Neulactil [IX] |

**periciazine 10 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3053Q NP | 1 | 5 | 0.00 | 23.04 | 24.58 | Neulactil [IX] |

### *Butyrophenone derivatives*

## HALOPERIDOL

**haloperidol 500 microgram tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2761H NP | 1 | 5 | 0.00 | 17.66 | 19.20 | Serenace [AS] |

**haloperidol 1.5 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2767P NP | 1 | 5 | 0.00 | 18.01 | 19.55 | Serenace [AS] |

**haloperidol 2 mg/mL oral liquid, 100 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2763K NP | ‡1 | 5 | 0.00 | 24.56 | 25.00 | Serenace [AS] |

**haloperidol 5 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2770T NP | 1 | 5 | 0.00 | 17.87 | 19.41 | Serenace [AS] |

**haloperidol 5 mg/mL injection, 10 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2768Q NP | 1 | 0 | 0.00 | 25.23 | 25.00 | [a] HALOPERIDOL MEDSURGE [DZ] | [a] Serenace [AS] |

## HALOPERIDOL DECANOATE

**haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2765M NP | 1 | 0 | 0.00 | 30.32 | 25.00 | Haldol decanoate [IX] |

**haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules**

| 2766N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 46.36 | 25.00 | Haldol decanoate [IX] |

***Indole derivatives***

## LURASIDONE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**
***4246***
Schizophrenia

**lurasidone hydrochloride 40 mg tablet, 30**

| 10526B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 29.50 | 25.00 | [a] APO-Lurasidone [TX] | [a] Lavione [AF] |
| | | | | | | [a] Lurasidone Lupin [GQ] | [a] Lurasidone Sandoz [SZ] |
| | | | | | | [a] LURASIDONE SUN [RA] | [a] LURASIDONE-WGR [WG] |
| | | | | | | [a] Pharmacor Lurasidone [CR] | |

**lurasidone hydrochloride 80 mg tablet, 30**

| 10529E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 44.65 | 25.00 | [a] APO-Lurasidone [TX] | [a] Lavione [AF] |
| | | | | | | [a] Lurasidone Lupin [GQ] | [a] Lurasidone Sandoz [SZ] |
| | | | | | | [a] LURASIDONE SUN [RA] | [a] LURASIDONE-WGR [WG] |
| | | | | | | [a] Pharmacor Lurasidone [CR] | |

## ZIPRASIDONE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**
***4246***
Schizophrenia
**Authority Required (STREAMLINED)**
***5742***
Acute mania or mixed episodes
**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

**ziprasidone 20 mg capsule, 60**

| 9070J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 43.05 | 25.00 | [a] Zeldox [GO] | [a] Ziprasidone GH [GQ] |
| | | | | | | [a] ZIPROX [RW] | |

**ziprasidone 40 mg capsule, 60**

| 9071K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 71.85 | 25.00 | [a] Zeldox [GO] | [a] Ziprasidone GH [GQ] |
| | | | | | | [a] ZIPROX [RW] | |

**ziprasidone 60 mg capsule, 60**

| 9072L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 100.27 | 25.00 | [a] Zeldox [GO] | [a] Ziprasidone GH [GQ] |
| | | | | | | [a] ZIPROX [RW] | |

**ziprasidone 80 mg capsule, 60**

| 9073M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 129.81 | 25.00 | [a] Zeldox [GO] | [a] Ziprasidone GH [GQ] |
| | | | | | | [a] ZIPROX [RW] | |

***Thioxanthene derivatives***

## FLUPENTIXOL DECANOATE

### flupentixol decanoate 20 mg/mL injection, 5 x 1 mL ampoules

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2255Q NP | 1 | 0 | 0.00 | 26.24 | 25.00 | Fluanxol Depot [LU] |

### flupentixol decanoate 100 mg/mL injection, 5 x 1 mL ampoules

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2257T NP | 1 | 0 | 0.00 | 50.59 | 25.00 | Fluanxol Concentrated Depot [LU] |

## ZUCLOPENTHIXOL DECANOATE

**Restricted benefit**

***15956***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

### zuclopenthixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8097E NP | 1 | 0 | 0.00 | 31.91 | 25.00 | Clopixol Depot [LU] |

## *Diazepines, oxazepines, thiazepines and oxepines*

## ASENAPINE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**

***4246***

Schizophrenia

**Authority Required (STREAMLINED)**

***5773***

Acute mania or mixed episodes

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be limited to up to 6 months per episode.

**Authority Required (STREAMLINED)**

***5719***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- The treatment must be as monotherapy.

### asenapine 5 mg sublingual wafer, 60

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5140M NP | 1 | 5 | 0.00 | 135.24 | 25.00 | Saphris [OQ] |

### asenapine 10 mg sublingual wafer, 60

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5141N NP | 1 | 5 | 0.00 | 219.21 | 25.00 | Saphris [OQ] |

## OLANZAPINE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**

***4246***

Schizophrenia

**Authority Required (STREAMLINED)**

***5869***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

### olanzapine 2.5 mg tablet, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8170B NP | 1 | 5 | 0.00 | 17.68 | 19.22 | [a] APO-OLANZAPINE [TX] | [a] Olanzapine RBX [RA] |

| 8170B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Olanzapine Sandoz [SZ] | [a] Ozin 2.5 [ZS] |
| | | | | | | [a] PRYZEX [RW] | [a] Zypine [AF] |
| | | | [B]7.66 | 25.34 | 19.22 | [a] Zyprexa [PB] | |

**olanzapine 5 mg tablet, 28**

| 8185T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-OLANZAPINE [TX] | [a] Olanzapine RBX [RA] |
| | | | | | | [a] Olanzapine Sandoz [SZ] | [a] Ozin 5 [ZS] |
| | | | | | | [a] PRYZEX [RW] | [a] Zypine [AF] |
| | | | [B]9.90 | 28.50 | 20.14 | [a] Zyprexa [PB] | |

**olanzapine 7.5 mg tablet, 28**

| 8186W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.81 | 20.35 | [a] APO-OLANZAPINE [TX] | [a] Olanzapine RBX [RA] |
| | | | | | | [a] Olanzapine Sandoz [SZ] | [a] Ozin 7.5 [ZS] |
| | | | | | | [a] PRYZEX [RW] | [a] Zypine [AF] |
| | | | [B]4.17 | 22.98 | 20.35 | [a] Zyprexa [PB] | |

**olanzapine 10 mg tablet, 28**

| 8187X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.21 | 21.75 | [a] APO-OLANZAPINE [TX] | [a] Olanzapine RBX [RA] |
| | | | | | | [a] Olanzapine Sandoz [SZ] | [a] Ozin 10 [ZS] |
| | | | | | | [a] PRYZEX [RW] | [a] Zypine [AF] |
| | | | [B]4.23 | 24.44 | 21.75 | [a] Zyprexa [PB] | |

## OLANZAPINE

**Caution** Monitor for post-injection syndrome for at least two hours after each injection.

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***4246***

Schizophrenia

**olanzapine 210 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack**

| 9294E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *314.64 | 25.00 | Zyprexa Relprevv [PB] |

**olanzapine 300 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack**

| 9295F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *506.12 | 25.00 | Zyprexa Relprevv [PB] |

**olanzapine 405 mg modified release injection [1 vial] (&) inert substance diluent [3 mL vial], 1 pack**

| 9303P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 337.59 | 25.00 | Zyprexa Relprevv [PB] |

## OLANZAPINE

**Note** Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**

***4246***

Schizophrenia

**Authority Required (STREAMLINED)**

***5869***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 5 mg orally disintegrating tablet, 28**

| 3381Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Olanzapine ODT [TX] | [a] Olanzapine Sandoz ODT 5 [SZ] |

| 3381Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] PRYZEX ODT [RW] | [a] Zypine ODT [AF] |

**olanzapine 5 mg wafer, 28**

| 8433W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 9.90 | 28.50 | 20.14 | [a] Zyprexa Zydis [PB] |

## OLANZAPINE

**Note** Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**

***4246***

Schizophrenia

**Authority Required (STREAMLINED)**

***5869***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 10 mg orally disintegrating tablet, 28**

| 3382B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.21 | 21.75 | [a] APO-Olanzapine ODT [TX] | [a] Olanzapine Sandoz ODT 10 [SZ] |
| | | | | | | [a] PRYZEX ODT [RW] | [a] Zypine ODT [AF] |

**olanzapine 10 mg wafer, 28**

| 8434X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 9.66 | 30.63 | 22.51 | [a] Zyprexa Zydis [PB] |

## OLANZAPINE

**Note** Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**

***4246***

Schizophrenia

**Authority Required (STREAMLINED)**

***5869***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 15 mg orally disintegrating tablet, 28**

| 3384D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 23.14 | 24.68 | [a] APO-Olanzapine ODT [TX] | [a] Olanzapine Sandoz ODT 15 [SZ] |
| | | | | | | [a] PRYZEX ODT [RW] | [a] Zypine ODT [AF] |

**olanzapine 15 mg wafer, 28**

| 8952E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 11.31 | 35.60 | 25.00 | [a] Zyprexa Zydis [PB] |

## OLANZAPINE

**Note** Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**

***4246***

Schizophrenia

**Authority Required (STREAMLINED)**

***5869***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**olanzapine 20 mg orally disintegrating tablet, 28**

| 3385E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 26.06 | 25.00 | [a] APO-Olanzapine ODT [TX] | [a] Olanzapine Sandoz ODT 20 [SZ] |
| | | | | | | [a] PRYZEX ODT [RW] | [a] Zypine ODT [AF] |

**olanzapine 20 mg wafer, 28**

| 8953F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 11.29 | 38.89 | 25.00 | [a] Zyprexa Zydis [PB] |

## QUETIAPINE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**

***4246***

Schizophrenia

**Authority Required (STREAMLINED)**

***5611***

Acute mania

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

**Authority Required (STREAMLINED)**

***5869***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**quetiapine 50 mg modified release tablet, 60**

| 9202H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.40 | 22.94 | [a] APX-Quetiapine XR [TY] | [a] QUETIAPINE-AS XR [RW] |
| | | | | | | [a] Quetiapine Sandoz XR [SZ] | [a] Quetia XR [OW] |
| | | | | | | [a] Tevatiapine XR [TB] | |
| | | | [B]9.17 | 30.57 | 22.94 | [a] Seroquel XR [AL] | |

**quetiapine 100 mg tablet, 90**

| 8457D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 24.32 | 25.00 | [a] APX-QUETIAPINE [TX] | [a] Blooms The Chemist Quetiapine [BG] |
| | | | | | | [a] Kaptan [ZS] | [a] Pharmacor Quetiapine 100 [CR] |
| | | | | | | [a] Quetia 100 [RW] | [a] Quetiapine RBX [RA] |
| | | | | | | [a] Quetiapine Sandoz Pharma [HX] | [a] QUETIAPINE-WGR [WG] |
| | | | | | | [a] Syquet [AF] | |
| | | | [B]9.17 | 33.49 | 25.00 | [a] Seroquel [AL] | |

**quetiapine 150 mg modified release tablet, 60**

| 5458G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 24.32 | 25.00 | [a] APX-Quetiapine XR [TY] | [a] Quetiapine Sandoz XR [SZ] |
| | | | | | | [a] Quetia XR [OW] | [a] Tevatiapine XR [TB] |
| | | | [B]15.02 | 39.34 | 25.00 | [a] Seroquel XR [AL] | |

**quetiapine 200 mg tablet, 60**

| 8458E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 27.93 | 25.00 | [a] APX-QUETIAPINE [TX] | [a] Blooms The Chemist Quetiapine [BG] |
| | | | | | | [a] Kaptan [ZS] | [a] Pharmacor Quetiapine 200 [CR] |
| | | | | | | [a] Quetia 200 [RW] | [a] Quetiapine RBX [RA] |
| | | | | | | [a] Quetiapine Sandoz Pharma [HX] | [a] QUETIAPINE-WGR [WG] |

| 8458E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Syquet [AF] | |
| | | | [B]9.17 | 37.10 | 25.00 | [a] Seroquel [AL] | |

**quetiapine 200 mg modified release tablet, 60**

| 9203J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 34.85 | 25.00 | [a] APX-Quetiapine XR [TY] | [a] QUETIAPINE-AS XR [RW] |
| | | | | | | [a] Quetiapine Sandoz XR [SZ] | [a] Quetia XR [OW] |
| | | | | | | [a] Tevatiapine XR [TB] | |
| | | | [B]9.17 | 44.02 | 25.00 | [a] Seroquel XR [AL] | |

**quetiapine 300 mg tablet, 60**

| 8580N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 34.28 | 25.00 | [a] APX-QUETIAPINE [TX] | [a] Blooms The Chemist Quetiapine [BG] |
| | | | | | | [a] Kaptan [ZS] | [a] Pharmacor Quetiapine 300 [CR] |
| | | | | | | [a] Quetia 300 [RW] | [a] Quetiapine RBX [RA] |
| | | | | | | [a] Quetiapine Sandoz Pharma [HX] | [a] QUETIAPINE-WGR [WG] |
| | | | | | | [a] Syquet [AF] | |
| | | | [B]9.17 | 43.45 | 25.00 | [a] Seroquel [AL] | |

**quetiapine 300 mg modified release tablet, 60**

| 9204K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 40.67 | 25.00 | [a] APX-Quetiapine XR [TY] | [a] QUETIAPINE-AS XR [RW] |
| | | | | | | [a] Quetiapine Sandoz XR [SZ] | [a] Quetia XR [OW] |
| | | | | | | [a] Tevatiapine XR [TB] | |
| | | | [B]9.17 | 49.84 | 25.00 | [a] Seroquel XR [AL] | |

**quetiapine 400 mg modified release tablet, 60**

| 9205L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 50.24 | 25.00 | [a] APX-Quetiapine XR [TY] | [a] QUETIAPINE-AS XR [RW] |
| | | | | | | [a] Quetiapine Sandoz XR [SZ] | [a] Quetia XR [OW] |
| | | | | | | [a] Tevatiapine XR [TB] | |
| | | | [B]9.17 | 59.41 | 25.00 | [a] Seroquel XR [AL] | |

## QUETIAPINE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Authority applications for increased repeats up to a maximum of 5 may be authorised for patients requiring dose optimisation for this condition not adequately provided by other strengths of this drug.

**Authority Required (STREAMLINED)**

***4246***

Schizophrenia

**Authority Required (STREAMLINED)**

***7927***

Acute mania

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy.

**Authority Required (STREAMLINED)**

***5869***

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

**quetiapine 25 mg tablet, 60**

| 8456C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 18.60 | 20.14 | [a] APX-QUETIAPINE [TX] | [a] Blooms The Chemist Quetiapine [BG] |
| | | | | | | [a] Kaptan [ZS] | [a] Pharmacor Quetiapine 25 [CR] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8456C | | | | | | [a] Quetia 25 [RW] | [a] Quetiapine RBX [RA] |
| | | | | | | [a] Quetiapine Sandoz Pharma [HX] | [a] QUETIAPINE-WGR [WG] |
| | | | | | | [a] Syquet [AF] | |
| | | | [B]10.71 | 29.31 | 20.14 | [a] Seroquel [AL] | |

## *Benzamides*

### AMISULPRIDE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**
***4246***
Schizophrenia

**amisulpride 100 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8594H | | | | | | | |
| NP | 1 | 5 | 0.00 | 19.35 | 20.89 | [a] Amisulpride Sandoz Pharma [HX] | [a] APO-Amisulpride [TX] |
| | | | | | | [a] Solian 100 [SW] | [a] Sulprix [AF] |

**amisulpride 100 mg/mL oral liquid, 60 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8736T | | | | | | |
| NP | 2 | 5 | 0.00 | *141.16 | 25.00 | Solian Solution [SW] |

**amisulpride 200 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8595J | | | | | | | |
| NP | 1 | 5 | 0.00 | 35.72 | 25.00 | [a] Amisulpride Sandoz Pharma [HX] | [a] AMISULPRIDE-WGR [WG] |
| | | | | | | [a] APO-Amisulpride [TX] | [a] Solian 200 [SW] |
| | | | | | | [a] Sulprix [AF] | |

**amisulpride 400 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8596K | | | | | | | |
| NP | 1 | 5 | 0.00 | 53.10 | 25.00 | [a] Amisulpride Sandoz Pharma [HX] | [a] AMISULPRIDE-WGR [WG] |
| | | | | | | [a] APO-Amisulpride [TX] | [a] Solian 400 [SW] |
| | | | | | | [a] Sulprix [AF] | |

## *Other antipsychotics*

### ARIPIPRAZOLE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**
***4246***
Schizophrenia

**aripiprazole 10 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8717T | | | | | | | |
| NP | 1 | 5 | 0.00 | 38.92 | 25.00 | [a] Abilify [OS] | [a] Abyraz [AF] |
| | | | | | | [a] APO-Aripiprazole [TX] | [a] Aripiprazole GH [GQ] |
| | | | | | | [a] Aripiprazole Sandoz [SZ] | [a] ARIPIPRAZOLE-WGR [WG] |
| | | | | | | [a] ARIZOLE [RW] | |

**aripiprazole 15 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8718W | | | | | | | |
| NP | 1 | 5 | 0.00 | 49.22 | 25.00 | [a] Abilify [OS] | [a] Abyraz [AF] |
| | | | | | | [a] APO-Aripiprazole [TX] | [a] Aripiprazole GH [GQ] |
| | | | | | | [a] Aripiprazole Sandoz [SZ] | [a] ARIPIPRAZOLE-WGR [WG] |
| | | | | | | [a] ARIZOLE [RW] | |

**aripiprazole 20 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8719X | | | | | | | |
| NP | 1 | 5 | 0.00 | 56.79 | 25.00 | [a] Abilify [OS] | [a] Abyraz [AF] |
| | | | | | | [a] APO-Aripiprazole [TX] | [a] Aripiprazole GH [GQ] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8719X | | | | | | [a] Aripiprazole Sandoz [SZ] | [a] ARIZOLE [RW] |

**aripiprazole 30 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8720Y | | | | | | | |
| NP | 1 | 5 | 0.00 | 66.06 | 25.00 | [a] Abilify [OS] | [a] Abyraz [AF] |
| | | | | | | [a] APO-Aripiprazole [TX] | [a] Aripiprazole GH [GQ] |
| | | | | | | [a] Aripiprazole Sandoz [SZ] | [a] ARIZOLE [RW] |

**aripiprazole 300 mg modified release injection [1 chamber] (&) inert substance diluent [1.2 mL chamber], 1 dual chamber syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15128F | | | | | | |
| NP | ‡1 | 5 | 0.00 | 285.73 | 25.00 | Abilify Maintena [LU] |

**aripiprazole 300 mg modified release injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10224D | | | | | | |
| NP | 1 | 5 | 0.00 | 285.73 | 25.00 | Abilify Maintena [LU] |

**aripiprazole 400 mg modified release injection [1 chamber] (&) inert substance diluent [1.6 mL chamber], 1 dual chamber syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15122X | | | | | | |
| NP | ‡1 | 5 | 0.00 | 354.83 | 25.00 | Abilify Maintena [LU] |

**aripiprazole 400 mg modified release injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 10219W | | | | | | | |
| NP | 1 | 5 | 0.00 | 354.83 | 25.00 | [a] Abilify Maintena [LU] | [a] ARIPENA [RA] |

## ARIPIPRAZOLE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Note** Patient dosage is to be determined as per the Therapeutic Goods Administration (TGA) approved Product Information.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16456***

Schizophrenia

**Clinical criteria:**

- Patient must have previously received and be stabilised on PBS-subsidised aripiprazole once-monthly injection.

**Aripiprazole 720 mg/2.4 mL modified release injection, 2.4 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14790K | | | | | | |
| NP | 1 | 2 | 0.00 | 562.10 | 25.00 | Abilify Asimtufii [LU] |

**Aripiprazole 960 mg/3.2 mL modified release injection, 3.2 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14824F | | | | | | |
| NP | 1 | 2 | 0.00 | 700.31 | 25.00 | Abilify Asimtufii [LU] |

## BREXPIPRAZOLE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**

***4246***

Schizophrenia

**brexpiprazole 500 microgram tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15097N | | | | | | |
| NP | 1 | 0 | 0.00 | 136.40 | 25.00 | Rexulti [LU] |

**brexpiprazole 1 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11189X | | | | | | |
| NP | 1 | 0 | 0.00 | 136.40 | 25.00 | Rexulti [LU] |

**brexpiprazole 2 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11188W | | | | | | |
| NP | 1 | 5 | 0.00 | 136.40 | 25.00 | Rexulti [LU] |

**brexpiprazole 3 mg tablet, 30**

| 11190Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 136.40 | 25.00 | Rexulti [LU] |

**brexpiprazole 4 mg tablet, 30**

| 11184P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 136.40 | 25.00 | Rexulti [LU] |

## CARIPRAZINE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**
***4246***
Schizophrenia

**cariprazine 1.5 mg capsule, 30**

| 12652X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 100.68 | 25.00 | Reagila [IX] |

**cariprazine 3 mg capsule, 30**

| 12619E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 100.68 | 25.00 | Reagila [IX] |

**cariprazine 4.5 mg capsule, 30**

| 12653Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 100.68 | 25.00 | Reagila [IX] |

**cariprazine 6 mg capsule, 30**

| 12622H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 100.68 | 25.00 | Reagila [IX] |

## PALIPERIDONE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**
***4246***
Schizophrenia

**paliperidone 3 mg modified release tablet, 28**

| 9140C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 55.13 | 25.00 | Invega [JC] |

**paliperidone 6 mg modified release tablet, 28**

| 9141D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 96.74 | 25.00 | Invega [JC] |

**paliperidone 9 mg modified release tablet, 28**

| 9142E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 139.10 | 25.00 | Invega [JC] |

**paliperidone 25 mg modified release injection, 1 syringe**

| 5100K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 94.16 | 25.00 | Invega Sustenna [JC] |

**paliperidone 50 mg modified release injection, 1 syringe**

| 5102M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 176.93 | 25.00 | Invega Sustenna [JC] |

**paliperidone 75 mg modified release injection, 1 syringe**

| 5103N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 227.35 | 25.00 | Invega Sustenna [JC] |

**paliperidone 100 mg modified release injection, 1 syringe**

| 5107T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 277.26 | 25.00 | Invega Sustenna [JC] |

**paliperidone 150 mg modified release injection, 1 syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5109X NP | 1 | 5 | 0.00 | 277.26 | 25.00 | Invega Sustenna [JC] |

## PALIPERIDONE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Note** Patient dosage is to be determined as per the dose transition table in the Product Information based on the maintenance dose of paliperidone once monthly injection.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***13049***

Schizophrenia

**Clinical criteria:**

- Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months; **OR**
- Patient must have previously received and be stabilised on PBS-subsidised paliperidone six-monthly injection for at least one cycle.

**paliperidone 175 mg/0.875 mL modified release injection, 0.875 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11085K NP | 1 | 1 | 0.00 | 512.08 | 25.00 | Invega Trinza [JC] |

**paliperidone 263 mg/1.315 mL modified release injection, 1.315 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11072R NP | 1 | 1 | 0.00 | 663.34 | 25.00 | Invega Trinza [JC] |

**paliperidone 350 mg/1.75 mL modified release injection, 1.75 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11094X NP | 1 | 1 | 0.00 | 813.06 | 25.00 | Invega Trinza [JC] |

**paliperidone 525 mg/2.625 mL modified release injection, 2.625 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11066K NP | 1 | 1 | 0.00 | 813.06 | 25.00 | Invega Trinza [JC] |

## PALIPERIDONE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Note** Patient dosage is to be determined as per the dose transition table in the Product Information based on the maintenance dose of paliperidone once monthly injection.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***13082***

Schizophrenia

**Clinical criteria:**

- Patient must have previously received and be stabilised on PBS-subsidised paliperidone three-monthly injection for at least one cycle; **OR**
- Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months.

**paliperidone 700 mg/3.5 mL modified release injection, 3.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13053B NP | 1 | 0 | 0.00 | 1,605.45 | 25.00 | Invega Hafyera [JC] |

**paliperidone 1 g/5 mL modified release injection, 5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13046P NP | 1 | 0 | 0.00 | 1,605.45 | 25.00 | Invega Hafyera [JC] |

## RISPERIDONE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**

***4246***

Schizophrenia

**risperidone 500 microgram tablet, 60**

| 8869T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 22.84 | 24.38 | [a] APO-Risperidone [TX] | [a] Ozidal [RA] |
| | | | | | | [a] Rispa [RW] | [a] Risperidone Sandoz [SZ] |
| | | | | | | [a] Rispernia [ZS] | [a] Rixadone [AF] |

## RISPERIDONE

**Authority Required (STREAMLINED)**

***6898***

Severe behavioural disturbances

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority Required (STREAMLINED)**

***16048***

Severe behavioural disturbances

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**

- Patient must be at least 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**risperidone 500 microgram tablet, 60**

| 8787L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 22.84 | 24.38 | [a] APO-Risperidone [TX] | [a] Ozidal [RA] |
| | | | | | | [a] Rispa [RW] | [a] Risperidone Sandoz [SZ] |
| | | | | | | [a] Rispernia [ZS] | [a] Rixadone [AF] |

**risperidone 1 mg tablet, 60**

| 8789N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 18.60 | 20.14 | [a] APO-Risperidone [TX] | [a] Ozidal [RA] |
| | | | | | | [a] Rispa [RW] | [a] Risperidone Sandoz [SZ] |
| | | | | | | [a] Rispernia [ZS] | [a] Rixadone [AF] |

**risperidone 1 mg/mL oral liquid, 100 mL**

| 9293D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | 0.00 | 112.78 | 25.00 | [a] Risperdal [JC] | [a] Risperidone Lupin [GQ] |
| | | | | | | [a] Rixadone [AF] | |

**risperidone 2 mg tablet, 60**

| 9079W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 20.85 | 22.39 | [a] APO-Risperidone [TX] | [a] Ozidal [RA] |
| | | | | | | [a] Rispa [RW] | [a] Risperidone Sandoz [SZ] |
| | | | | | | [a] Rispernia [ZS] | [a] Rixadone [AF] |

## RISPERIDONE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**

***4246***

Schizophrenia

**Authority Required (STREAMLINED)**

***5907***

Acute mania

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as adjunctive therapy to mood stabilisers, **AND**
- The treatment must be limited to up to 6 months per episode.

**risperidone 1 mg tablet, 60**

| 3169T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Risperidone [TX] | [a] Ozidal [RA] |
| | | | | | | [a] Rispa [RW] | [a] Risperidone Sandoz [SZ] |
| | | | | | | [a] Rispernia [ZS] | [a] Rixadone [AF] |

**risperidone 1 mg/mL oral liquid, 100 mL**

| 8100H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 112.78 | 25.00 | [a] Risperdal [JC] | [a] Risperidone Lupin [GQ] |
| | | | | | | [a] Rixadone [AF] | |

**risperidone 2 mg tablet, 60**

| 3170W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.85 | 22.39 | [a] APO-Risperidone [TX] | [a] Ozidal [RA] |
| | | | | | | [a] Rispa [RW] | [a] Risperidone Sandoz [SZ] |
| | | | | | | [a] Rispernia [ZS] | [a] Rixadone [AF] |

**risperidone 3 mg tablet, 60**

| 3171X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 24.37 | 25.00 | [a] APO-Risperidone [TX] | [a] Ozidal [RA] |
| | | | | | | [a] Rispa [RW] | [a] Risperidone Sandoz [SZ] |
| | | | | | | [a] Rispernia [ZS] | [a] Rixadone [AF] |

**risperidone 4 mg tablet, 60**

| 3172Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 27.87 | 25.00 | [a] APO-Risperidone [TX] | [a] Rispa [RW] |
| | | | | | | [a] Risperidone Sandoz [SZ] | [a] Rispernia [ZS] |
| | | | | | | [a] Rixadone [AF] | |

## RISPERIDONE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**

***4246***

Schizophrenia

**Authority Required (STREAMLINED)**

***5912***

Bipolar I disorder

**Clinical criteria:**

- The condition must be refractory to treatment, **AND**
- The treatment must be in combination with lithium or sodium valproate, **AND**
- The treatment must be maintenance therapy.

**risperidone 25 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

| 8780D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *182.12 | 25.00 | Risperdal Consta [JC] |

**risperidone 37.5 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

| 8781E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *234.34 | 25.00 | Risperdal Consta [JC] |

**risperidone 50 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

| 8782F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *285.98 | 25.00 | Risperdal Consta [JC] |

## RISPERIDONE

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***10020***

Behavioural disturbances

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A patient may only qualify for 12 weeks of PBS-subsidised treatment under this restriction once in a 12 month period.

### risperidone 500 microgram tablet, 60

| 11869Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 22.84 | 24.38 | [a] APO-Risperidone [TX] | [a] Ozidal [RA] |
| | | | | | | [a] Rispa [RW] | [a] Risperidone Sandoz [SZ] |
| | | | | | | [a] Rispernia [ZS] | [a] Rixadone [AF] |

### risperidone 1 mg tablet, 60

| 11877D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 18.60 | 20.14 | [a] APO-Risperidone [TX] | [a] Ozidal [RA] |
| | | | | | | [a] Rispa [RW] | [a] Risperidone Sandoz [SZ] |
| | | | | | | [a] Rispernia [ZS] | [a] Rixadone [AF] |

### risperidone 1 mg/mL oral liquid, 100 mL

| 11874Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | 0.00 | 112.78 | 25.00 | [a] Risperdal [JC] | [a] Risperidone Lupin [GQ] |
| | | | | | | [a] Rixadone [AF] | |

## RISPERIDONE

**Caution** In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***10021***

Behavioural disturbances

Treatment Phase: Continuing treatment, trial of dose reduction or cessation of treatment

**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have responded to an initial course of treatment with this drug for this condition, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; **OR**
- Patient must have trialled a period of treatment reduction or cessation with this drug for this condition and experienced worsening or re-emergence of symptoms during this trial, and retrials are considered periodically, **AND**
- Patient must be optimised on non-pharmacological methods of treatment.

The patient's response to treatment and a trial of treatment reduction or cessation must be discussed formally with a psychiatrist or geriatrician or in a documented clinical review process involving a least one other medical practitioner, or be reviewed by a psychiatrist or geriatrician.

Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression.

Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy.

Patients must be monitored for adverse effects such as falls, drowsiness leading to reduced self-care, incontinence, reduced nutrition, reduced ability to communicate needs/wishes and take part in activities. Therapy must be ceased if harms of therapy outweigh benefits.

Trials of reduction or cessation of therapy should be considered periodically with the intention of maintaining symptom control through non-pharmacological measures wherever possible and/or lowest effective dose therapy.

Evidence of patient benefit from therapy, failure of non-pharmacological approaches to manage symptoms in the absence of therapy, and recurrence of symptoms following reduction or cessation of therapy, trialled on at least 1 occasion, must be documented in the patient's medical records.

**risperidone 500 microgram tablet, 60**

| 11881H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 22.84 | 24.38 | [a] APO-Risperidone [TX] | [a] Ozidal [RA] |
| | | | | | | [a] Rispa [RW] | [a] Risperidone Sandoz [SZ] |
| | | | | | | [a] Rispernia [ZS] | [a] Rixadone [AF] |

**risperidone 1 mg tablet, 60**

| 11879F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 18.60 | 20.14 | [a] APO-Risperidone [TX] | [a] Ozidal [RA] |
| | | | | | | [a] Rispa [RW] | [a] Risperidone Sandoz [SZ] |
| | | | | | | [a] Rispernia [ZS] | [a] Rixadone [AF] |

**risperidone 1 mg/mL oral liquid, 100 mL**

| 11882J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | 0.00 | 112.78 | 25.00 | [a] Risperdal [JC] | [a] Risperidone Lupin [GQ] |
| | | | | | | [a] Rixadone [AF] | |

## RISPERIDONE

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***16231***

Schizophrenia

For a patient switching from oral risperidone, the prescriber must determine the patient dosage of this drug based on the current dose of oral risperidone according to the dose transition table in the Therapeutic Goods Administration (TGA) approved Product Information.

**risperidone 75 mg modified release injection [1 syringe] (&) inert substance diluent [0.383 mL syringe], 1 pack**

| 14686Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 210.00 | 25.00 | Risvan [SE] |

## RISPERIDONE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** For the purpose of administering this restriction, Schizophrenia refers to schizophrenia spectrum disorders outlined in the DSM-5 criteria.

**Authority Required (STREAMLINED)**

***16231***

Schizophrenia

For a patient switching from oral risperidone, the prescriber must determine the patient dosage of this drug based on the current dose of oral risperidone according to the dose transition table in the Therapeutic Goods Administration (TGA) approved Product Information.

**risperidone 100 mg modified release injection [1 syringe] (&) inert substance diluent [0.49 mL syringe], 1 pack**

| 14688C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 255.94 | 25.00 | Risvan [SE] |

# ANXIOLYTICS

## *Benzodiazepine derivatives*

## ALPRAZOLAM

**Authority Required**

***6773***

Panic disorder

**Clinical criteria:**

- The treatment must be for use when other treatments have failed; **OR**
- The treatment must be for use when other treatments are inappropriate.

**Note** The panic disorder must not be attributable to some known organic factor.

**Note** No increase in the maximum number of repeats may be authorised.

**alprazolam 250 microgram tablet, 10**

| 11205R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 22.83 | 24.37 | Kalma 0.25 [AF] |

**alprazolam 500 microgram tablet, 10**

| 11187T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 23.29 | 24.83 | [a] Alprax 0.5 [AS] | [a] Kalma 0.5 [AF] |

**alprazolam 1 mg tablet, 10**

| 11186R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 23.83 | 25.00 | [a] Alprax 1 [AS] | [a] Kalma 1 [AF] |

## DIAZEPAM

**diazepam 2 mg tablet, 50**

| 5071X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APX-Diazepam [TY] | [a] DIAZEPAM-WGR [WG] |
| | | | | | | [a] Valpam 2 [RW] | |
| | | | [B]2.78 | 19.88 | 18.64 | [a] Antenex 2 [AF] | |

**diazepam 5 mg tablet, 50**

| 5072Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Antenex 5 [AF] | [a] APX-Diazepam [TY] |
| | | | | | | [a] DIAZEPAM-WGR [WG] | [a] Valpam 5 [RW] |
| | | | [B]3.07 | 20.17 | 18.64 | [a] Valium [IX] | |

## DIAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for

(i) the treatment of disabling spasticity; or

(ii) malignant neoplasia (late stage); or

(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or

(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

**diazepam 2 mg tablet, 50**

| 3161J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APX-Diazepam [TY] | [a] DIAZEPAM-WGR [WG] |
| | | | | | | [a] Valpam 2 [RW] | |
| | | | [B]2.78 | 19.88 | 18.64 | [a] Antenex 2 [AF] | |

**diazepam 5 mg tablet, 50**

| 3162K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Antenex 5 [AF] | [a] APX-Diazepam [TY] |
| | | | | | | [a] DIAZEPAM-WGR [WG] | [a] Valpam 5 [RW] |
| | | | [B]3.07 | 20.17 | 18.64 | [a] Valium [IX] | |

## DIAZEPAM

**Authority Required**

***4244***

Chronic spasticity

**Population criteria:**

- Patient must be under 18 years of age.

**diazepam 10 mg/10 mL oral liquid, 100 mL**

| 2669L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 45.26 | 25.00 | Diazepam Elixir [ON] |

## OXAZEPAM

**oxazepam 15 mg tablet, 25**

| 5192G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Alepam 15 [AF] | [a] Serepax [AS] |

**oxazepam 30 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5193H DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Alepam 30 [AF] | [a] APO-Oxazepam [TX] |
| | | | | | | [a] OXAZEPAM-WGR [WG] | |
| | | | [B]0.80 | 17.90 | 18.64 | [a] Murelax [RW] | |
| | | | [B]3.70 | 20.80 | 18.64 | [a] Serepax [AS] | |

## OXAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of oxazepam.

**oxazepam 15 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3132W NP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Alepam 15 [AF] | [a] Serepax [AS] |

**oxazepam 30 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3133X NP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Alepam 30 [AF] | [a] APO-Oxazepam [TX] |
| | | | | | | [a] OXAZEPAM-WGR [WG] | |
| | | | [B]0.80 | 17.90 | 18.64 | [a] Murelax [RW] | |
| | | | [B]3.70 | 20.80 | 18.64 | [a] Serepax [AS] | |

## OXAZEPAM

**Authority Required**

***6217***

Malignant neoplasia (late stage)

**Authority Required**

***6230***

Anxiety

**Clinical criteria:**

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority Required**

***6262***

Anxiety

**Clinical criteria:**

- Patient must be receiving this drug for the management of anxiety, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**oxazepam 15 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3134Y NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Alepam 15 [AF] | [a] Serepax [AS] |

**oxazepam 30 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 3135B NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Alepam 30 [AF] | [a] APO-Oxazepam [TX] |
| | | | | | | [a] OXAZEPAM-WGR [WG] | |
| | | | [B]1.60 | 21.44 | 21.38 | [a] Murelax [RW] | |
| | | | [B]7.40 | 27.24 | 21.38 | [a] Serepax [AS] | |

# HYPNOTICS AND SEDATIVES

## *Benzodiazepine derivatives*

## MIDAZOLAM

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***18840***

Generalized convulsive status epilepticus

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of status epilepticus, **AND**
- Patient must have experienced at least one prolonged seizure (greater than 5 minutes duration) requiring emergency medical attention within the previous 5 years.

**Population criteria:**

- Patient must be at least six months of age.

**Clinical criteria:**

- The treatment must be initiated by a specialist physician experienced in the treatment of epilepsy.

At the time of the authority application, medical practitioners should request the appropriate quantity to cater for the patient's circumstances.

Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures.

**midazolam 2.5 mg/0.25 mL oral liquid, 0.25 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15388X | 2 | 1 | 0.00 | *272.20 | 25.00 | Zyamis [IX] |

**midazolam 5 mg/0.5 mL oral liquid, 0.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14292F | 2 | 1 | 0.00 | *272.20 | 25.00 | Zyamis [IX] |

**midazolam 7.5 mg/0.75 mL oral liquid, 0.75 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14238J | 2 | 1 | 0.00 | *272.20 | 25.00 | Zyamis [IX] |

**midazolam 10 mg/mL oral liquid, 1 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14270C | 2 | 1 | 0.00 | *272.20 | 25.00 | Zyamis [IX] |

## MIDAZOLAM

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15456***

Generalized convulsive status epilepticus

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

At the time of the authority application, practitioners should request the appropriate quantity to cater for the patient's circumstances.

Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures.

**midazolam 2.5 mg/0.25 mL oral liquid, 0.25 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15381M | 2 | 1 | 0.00 | *272.20 | 25.00 | Zyamis [IX] |
| NP | | | | | | |

**midazolam 5 mg/0.5 mL oral liquid, 0.5 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14293G | 2 | 1 | 0.00 | *272.20 | 25.00 | Zyamis [IX] |
| NP | | | | | | |

**midazolam 7.5 mg/0.75 mL oral liquid, 0.75 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14291E | 2 | 1 | 0.00 | *272.20 | 25.00 | Zyamis [IX] |
| NP | | | | | | |

**midazolam 10 mg/mL oral liquid, 1 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14299N | 2 | 1 | 0.00 | *272.20 | 25.00 | Zyamis [IX] |
| NP | | | | | | |

## NITRAZEPAM

**nitrazepam 5 mg tablet, 25**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5189D | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Alodorm [AF] | [a] Mogadon [IL] |
| DP | | | | | | | |

## NITRAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of nitrazepam.

### nitrazepam 5 mg tablet, 25

| 2723H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] Alodorm [AF] | [a] Mogadon [IL] |

## NITRAZEPAM

**Authority Required**

***16653***

Myoclonic epilepsy

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required**

***16692***

Malignant neoplasia (late stage)

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required**

***5950***

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority Required**

***5941***

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

### nitrazepam 5 mg tablet, 25

| 2732T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] Alodorm [AF] | [a] Mogadon [IL] |

## TEMAZEPAM

### temazepam 10 mg tablet, 25

| 5221T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Temazepam [TX] | [a] Temaze [AF] |
| | | | | | | [a] TEMAZEPAM-WGR [WG] | [a] Temtabs [LN] |
| | | | [B]4.81 | 21.91 | 18.64 | [a] Normison [AS] | |

## TEMAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam.

**Restricted benefit**

***16279***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife where patient care is being shared with a medical practitioner.

**temazepam 10 mg tablet, 25**

| 2089Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 17.10 | 18.64 | [a] APO-Temazepam [TX] | [a] Temaze [AF] |
| | | | | | | [a] TEMAZEPAM-WGR [WG] | [a] Temtabs [LN] |
| | | | [B]4.81 | 21.91 | 18.64 | [a] Normison [AS] | |

## TEMAZEPAM

**Authority Required**

***16692***

Malignant neoplasia (late stage)

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**Authority Required**

***5950***

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority Required**

***5941***

Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**temazepam 10 mg tablet, 25**

| 2088X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *19.84 | 21.38 | [a] APO-Temazepam [TX] | [a] Temaze [AF] |
| | | | | | | [a] TEMAZEPAM-WGR [WG] | [a] Temtabs [LN] |
| | | | [B]9.62 | 29.46 | 21.38 | [a] Normison [AS] | |

### *Melatonin receptor agonists*

## MELATONIN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** A developmental specialist is a medical practitioner who is a member of the Neurodevelopmental and Behavioural Paediatric Society of Australasia.

**Note** Increases in the maximum quantity to provide sufficient treatment duration for 30 days treatment per dispensing at the maximum recommended dose as per the approved Product Information, may be sought.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15333***

Insomnia

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have Smith-Magenis Syndrome confirmed by genetic testing, **AND**
- The condition must be inadequately responsive to sleep hygiene measures, resulting in the patient experiencing a period of at least 12 consecutive weeks of impaired sleep (see definition of impaired sleep below).

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as at least one of: (i) a paediatrician, (ii) a sleep physician, (iii) neurologist, (iv) a psychiatrist, (v) a developmental specialist (see NOTE); this authority approval is being sought by one of these 5 prescriber types.

**Population criteria:**

- Patient must be at least 2 years of age, but yet to turn 18 years of age, at treatment initiation with this drug.

Definition:

For the purposes of administering this restriction, Smith-Magenis Syndrome is confirmed by the deletion or variation of the retinoic acid induced 1 (RAI1) gene on chromosome 17p11.2

Definition:

For the purposes of administering this restriction, impaired sleep is at least one of:

(i) less than 6 hours of continuous sleep on at least 3 occasions over a given 5-day interval;

(ii) taking at least half an hour to fall asleep on at least 3 occasions over a given 5-day interval.

Prior to seeking authorisation for this pharmaceutical benefit, document the amount of continuous sleep/sleep latency in the patient's medical records for a period of 2 consecutive weeks, but ensure the impairment has been observed for at least 12 consecutive weeks. The documented values (averages) will form baseline measurements upon which the extent of response to treatment is to be considered under the Continuing treatment listing.

The observations of continuous sleep/sleep latency may be based on any of the following, including a mix of: patient self-reporting, parental observation, documented medical history, sleep studies conducted by health professionals.

**Authority Required**

***15363***

Insomnia

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have experienced/maintained a clinically meaningful response (as defined below) to the preceding supply of this drug - document the response improvement in the patient's medical records, **AND**
- The treatment must have commenced between the ages of 2 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as at least one of: (i) a paediatrician, (ii) a sleep physician, (iii) neurologist, (iv) a psychiatrist, (v) a developmental specialist (see NOTE); this authority approval is being sought by one of these 5 prescriber types; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Treatment must cease if a patient is unable to achieve a clinically meaningful response on the maximum dose of melatonin specified in the Product Information.

Definition:

A clinically meaningful response to this drug is defined as at least one of:

(i) an increase in total sleep time of at least 45 minutes per night on average from baseline;

(ii) a decrease in the time it takes to fall asleep by at least 15 minutes per night on average from baseline.

**melatonin 1 mg modified release tablet, 60**

| 14188R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 71.73 | 25.00 | Slenyto [AS] |

**melatonin 5 mg modified release tablet, 30**

| 14211Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 151.73 | 25.00 | Slenyto [AS] |

# PSYCHOANALEPTICS

## ANTIDEPRESSANTS

### *Non-selective monoamine reuptake inhibitors*

### AMITRIPTYLINE

**amitriptyline hydrochloride 10 mg tablet, 50**

| 2417F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 17.43 | 18.97 | [a] Amitriptyline Lupin [GQ] | [a] Amitriptyline Viatris 10 [AL] |
| | | | | | | [a] AMITRIPTYLINE-WGR [WG] | [a] APX-Amitriptyline [TY] |
| | | | | | | [a] ENTRIP [RW] | |
| | | | [B]1.82 | 19.25 | 18.97 | [a] Endep 10 [AF] | |

**amitriptyline hydrochloride 25 mg tablet, 50**

| 2418G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 17.61 | 19.15 | [a] Amitriptyline Lupin [GQ] | [a] Amitriptyline Viatris 25 [AL] |
| | | | | | | [a] AMITRIPTYLINE-WGR [WG] | [a] APX-Amitriptyline [TY] |
| | | | | | | [a] ENTRIP [RW] | |
| | | | [B]1.82 | 19.43 | 19.15 | [a] Endep 25 [AF] | |

**amitriptyline hydrochloride 50 mg tablet, 50**

| 2429W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 17.98 | 19.52 | [a] Amitriptyline Lupin [GQ] | [a] Amitriptyline Viatris 50 [AL] |
| | | | | | | [a] APX-Amitriptyline [TY] | [a] ENTRIP [RW] |

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2429W | | | [B]1.82 | 19.80 | 19.52 | [a] Endep 50 [AF] | |

## CLOMIPRAMINE

**Restricted benefit**

***6250***

Cataplexy

**Clinical criteria:**

- The condition must be associated with narcolepsy.

**Restricted benefit**

***6251***

Obsessive-compulsive disorder

**Restricted benefit**

***6299***

Phobic disorders

**Population criteria:**

- Patient must be an adult.

### clomipramine hydrochloride 25 mg tablet, 50

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1561E | | | | | | | |
| NP | 1 | 2 | 0.00 | 19.25 | 20.79 | [a] APO-Clomipramine [TX] | [a] CLOMIPRAMINE-WGR [WG] |
| | | | | | | [a] Placil [AF] | |
| | | | [B]3.57 | 22.82 | 20.79 | [a] Anafranil 25 [PB] | |

## DOSULEPIN (DOTHIEPIN)

### dosulepin (dothiepin) hydrochloride 25 mg capsule, 50

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1357K | | | | | | | |
| NP | 1 | 2 | 0.00 | 17.49 | 19.03 | [a] Dosulepin Viatris [MQ] | |
| | | | [B]1.81 | 19.30 | 19.03 | [a] Dothep 25 [AF] | |

### dosulepin (dothiepin) hydrochloride 75 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1358L | | | | | | | |
| NP | 1 | 2 | 0.00 | 17.49 | 19.03 | [a] Dosulepin Viatris 75 [AL] | |
| | | | [B]1.81 | 19.30 | 19.03 | [a] Dothep 75 [AF] | |

## IMIPRAMINE

### imipramine hydrochloride 10 mg tablet, 50

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2420J | | | | | | |
| NP | 1 | 2 | 0.00 | 18.57 | 20.11 | Tofranil 10 [GH] |

## IMIPRAMINE

**Note** Pharmaceutical benefits that have the form imipramine hydrochloride 25 mg tablet in a pack size of 50 can be substituted for a pack size of 100 in the case of a shortage.

### imipramine hydrochloride 25 mg tablet, 50

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2421K | | | | | | |
| NP | 1 | 2 | 0.00 | 21.78 | 23.32 | [a] Tofranil 25 [GH] |

### imipramine hydrochloride 25 mg tablet, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12113M | | | | | | |
| NP | 0.5 | 2 | 0.00 | *28.19 | 25.00 | [a] Imipramine (Leading) [QY] |

## NORTRIPTYLINE

**Restricted benefit**

***6235***

Major depression

**Clinical criteria:**

- The treatment must be for use when other anti-depressant therapy has failed.

**Restricted benefit**

***6300***

Major depression

**Clinical criteria:**

- The treatment must be for use when other anti-depressant therapy is contraindicated.

**nortriptyline 10 mg tablet, 50**

| 2522R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 18.65 | 20.19 | Allegron [RW] |

**nortriptyline 25 mg tablet, 50**

| 2523T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 20.06 | 21.60 | Allegron [RW] |

## *Selective serotonin reuptake inhibitors*

### CITALOPRAM

**Restricted benefit**
***4755***
Major depressive disorders

**citalopram 10 mg tablet, 28**

| 8702B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] Celapram [AF] | [a] CITALOPRAM-WGR [WG] |
| | | | | | | [a] Talam [RW] | |

**citalopram 20 mg tablet, 28**

| 8220P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Citalopram [TX] | [a] APX-Citalopram [TY] |
| | | | | | | [a] Celapram [AF] | [a] Citalopram Sandoz [SZ] |
| | | | | | | [a] CITALOPRAM-WGR [WG] | [a] Talam [RW] |
| | | | [B]12.64 | 29.74 | 18.64 | [a] Cipramil [LU] | |

**citalopram 40 mg tablet, 28**

| 8703C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.14 | 18.68 | [a] APO-Citalopram [TX] | [a] Celapram [AF] |
| | | | | | | [a] Citalopram Sandoz [SZ] | [a] CITALOPRAM-WGR [WG] |
| | | | | | | [a] Talam [RW] | |

### CITALOPRAM

**Restricted benefit**
***15666***
Major depressive disorders
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**citalopram 10 mg tablet, 28**

| 14313H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *19.84 | 21.38 | [a] Celapram [AF] | [a] CITALOPRAM-WGR [WG] |
| | | | | | | [a] Talam [RW] | |

**citalopram 20 mg tablet, 28**

| 14490P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *19.84 | 21.38 | [a] APO-Citalopram [TX] | [a] APX-Citalopram [TY] |
| | | | | | | [a] Celapram [AF] | [a] Citalopram Sandoz [SZ] |
| | | | | | | [a] CITALOPRAM-WGR [WG] | [a] Talam [RW] |
| | | | [B]25.28 | 45.12 | 21.38 | [a] Cipramil [LU] | |

**citalopram 40 mg tablet, 28**

| 14518D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *19.92 | 21.46 | [a] APO-Citalopram [TX] | [a] Celapram [AF] |
| | | | | | | [a] Citalopram Sandoz [SZ] | [a] CITALOPRAM-WGR [WG] |
| | | | | | | [a] Talam [RW] | |

### ESCITALOPRAM

**Restricted benefit**
***4755***
Major depressive disorders

**escitalopram 10 mg tablet, 28**

| 8700X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Escitalopram [TX] | [a] APX-Escitalopram [TY] |
| | | | | | | [a] Blooms Escitalopram [BG] | [a] Cilopam-S [ZS] |
| | | | | | | [a] ESCIT [DZ] | [a] Escitalopram GH [HQ] |
| | | | | | | [a] Escitalopram Sandoz [HX] | [a] ESCITALOPRAM-WGR [WG] |
| | | | | | | [a] Lexam 10 [RW] | [a] LoxaLate [AF] |
| | | | [B]13.65 | 30.75 | 18.64 | [a] Lexapro [LU] | |

**escitalopram 20 mg tablet, 28**

| 8701Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Escitalopram [TX] | [a] APX-Escitalopram [TY] |
| | | | | | | [a] Blooms Escitalopram [BG] | [a] Cilopam-S [ZS] |
| | | | | | | [a] ESCIT [DZ] | [a] Escitalopram GH [HQ] |
| | | | | | | [a] Escitalopram Sandoz [HX] | [a] ESCITALOPRAM-WGR [WG] |
| | | | | | | [a] Lexam 20 [RW] | [a] LoxaLate [AF] |
| | | | [B]13.98 | 31.08 | 18.64 | [a] Lexapro [LU] | |

## ESCITALOPRAM

**Restricted benefit**

***15666***

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**escitalopram 10 mg tablet, 28**

| 14349F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *19.84 | 21.38 | [a] APO-Escitalopram [TX] | [a] APX-Escitalopram [TY] |
| | | | | | | [a] Blooms Escitalopram [BG] | [a] Cilopam-S [ZS] |
| | | | | | | [a] ESCIT [DZ] | [a] Escitalopram GH [HQ] |
| | | | | | | [a] Escitalopram Sandoz [HX] | [a] ESCITALOPRAM-WGR [WG] |
| | | | | | | [a] Lexam 10 [RW] | [a] LoxaLate [AF] |
| | | | [B]27.30 | 47.14 | 21.38 | [a] Lexapro [LU] | |

**escitalopram 20 mg tablet, 28**

| 14415Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *19.84 | 21.38 | [a] APO-Escitalopram [TX] | [a] APX-Escitalopram [TY] |
| | | | | | | [a] Blooms Escitalopram [BG] | [a] Cilopam-S [ZS] |
| | | | | | | [a] ESCIT [DZ] | [a] Escitalopram GH [HQ] |
| | | | | | | [a] Escitalopram Sandoz [HX] | [a] ESCITALOPRAM-WGR [WG] |
| | | | | | | [a] Lexam 20 [RW] | [a] LoxaLate [AF] |
| | | | [B]27.96 | 47.80 | 21.38 | [a] Lexapro [LU] | |

## ESCITALOPRAM

**Restricted benefit**

***4703***

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

***4756***

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

***4757***

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

***4690***

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**escitalopram 10 mg tablet, 28**

| 9432K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Escitalopram [TX] | [a] APX-Escitalopram [TY] |
| | | | | | | [a] Blooms Escitalopram [BG] | [a] ESCIT [DZ] |
| | | | | | | [a] Escitalopram GH [HQ] | [a] Escitalopram Sandoz [HX] |
| | | | | | | [a] ESCITALOPRAM-WGR [WG] | [a] Lexam 10 [RW] |
| | | | | | | [a] LoxaLate [AF] | |
| | | | [B]13.65 | 30.75 | 18.64 | [a] Lexapro [LU] | |

**escitalopram 20 mg tablet, 28**

| 9433L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Escitalopram [TX] | [a] APX-Escitalopram [TY] |
| | | | | | | [a] Blooms Escitalopram [BG] | [a] ESCIT [DZ] |
| | | | | | | [a] Escitalopram GH [HQ] | [a] Escitalopram Sandoz [HX] |
| | | | | | | [a] ESCITALOPRAM-WGR [WG] | [a] Lexam 20 [RW] |
| | | | | | | [a] LoxaLate [AF] | |
| | | | [B]13.98 | 31.08 | 18.64 | [a] Lexapro [LU] | |

## ESCITALOPRAM

**Restricted benefit**

***15669***

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

***15550***

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

***15551***

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

***15696***

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**escitalopram 10 mg tablet, 28**

| 14519E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *19.84 | 21.38 | [a] APO-Escitalopram [TX] | [a] APX-Escitalopram [TY] |
| | | | | | | [a] Blooms Escitalopram [BG] | [a] ESCIT [DZ] |
| | | | | | | [a] Escitalopram GH [HQ] | [a] Escitalopram Sandoz [HX] |
| | | | | | | [a] ESCITALOPRAM-WGR [WG] | [a] Lexam 10 [RW] |
| | | | | | | [a] LoxaLate [AF] | |
| | | | [B]27.30 | 47.14 | 21.38 | [a] Lexapro [LU] | |

**escitalopram 20 mg tablet, 28**

| 14416R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *19.84 | 21.38 | [a] APO-Escitalopram [TX] | [a] APX-Escitalopram [TY] |
| | | | | | | [a] Blooms Escitalopram [BG] | [a] ESCIT [DZ] |
| | | | | | | [a] Escitalopram GH [HQ] | [a] Escitalopram Sandoz [HX] |
| | | | | | | [a] ESCITALOPRAM-WGR [WG] | [a] Lexam 20 [RW] |
| | | | | | | [a] LoxaLate [AF] | |
| | | | [B]27.96 | 47.80 | 21.38 | [a] Lexapro [LU] | |

## ESCITALOPRAM

**Restricted benefit**

***4680***

Major depressive disorders

**Restricted benefit**

***4747***

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

***4707***

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

***4721***

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

***4681***

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

### escitalopram 20 mg/mL oral liquid, 15 mL

| 10181W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 39.55 | 25.00 | Lexapro [LU] |

## ESCITALOPRAM

**Restricted benefit**

***15639***

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

***15606***

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

***15670***

Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**

***15751***

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

***15698***

Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**escitalopram 20 mg/mL oral liquid, 15 mL**

| 14546N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 2 | 0.00 | *64.74 | 25.00 | Lexapro [LU] |

## FLUOXETINE

**Restricted benefit**

***4755***

Major depressive disorders

**Restricted benefit**

***6277***

Obsessive-compulsive disorder

**fluoxetine 20 mg capsule, 28**

| 1434L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APO-Fluoxetine [TX] | [a] Blooms the Chemist Fluoxetine [BG] |
| | | | | | | [a] FLUOTEX [RF] | [a] Fluoxetine generichealth [GQ] |
| | | | | | | [a] Fluoxetine Sandoz [SZ] | [a] FLUOXETINE-WGR [WG] |
| | | | | | | [a] Zactin [AF] | |

**fluoxetine 20 mg tablet, 28**

| 8270G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | Zactin Tablet [AF] |

## FLUOXETINE

**Restricted benefit**

***15666***

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

***15582***

Obsessive-compulsive disorder

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**fluoxetine 20 mg capsule, 28**

| 14548Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *21.84 | 23.38 | [a] APO-Fluoxetine [TX] | [a] Blooms the Chemist Fluoxetine [BG] |
| | | | | | | [a] FLUOTEX [RF] | [a] Fluoxetine generichealth [GQ] |
| | | | | | | [a] Fluoxetine Sandoz [SZ] | [a] FLUOXETINE-WGR [WG] |
| | | | | | | [a] Zactin [AF] | |

**fluoxetine 20 mg tablet, 28**

| 14717N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *21.84 | 23.38 | Zactin Tablet [AF] |

## FLUVOXAMINE

**Restricted benefit**

***4755***

Major depressive disorders

**Restricted benefit**

***6277***

Obsessive-compulsive disorder

**fluvoxamine maleate 50 mg tablet, 30**

| 8512B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.86 | 21.40 | [a] APO-Fluvoxamine [TX] | [a] Faverin 50 [RW] |
| | | | | | | [a] FLUVOXAMINE-WGR [WG] | [a] Movox 50 [AL] |
| | | | [B]3.39 | 23.25 | 21.40 | [a] Luvox [GO] | |

**fluvoxamine maleate 100 mg tablet, 30**

| 8174F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 22.67 | 24.21 | [a] APO-Fluvoxamine [TX] | [a] Faverin 100 [RW] |
| | | | | | | [a] FLUVOXAMINE-WGR [WG] | [a] Movox 100 [AF] |
| | | | [B]3.40 | 26.07 | 24.21 | [a] Luvox [GO] | |

## FLUVOXAMINE

**Restricted benefit**

***15666***

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

***15582***

Obsessive-compulsive disorder

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**fluvoxamine maleate 50 mg tablet, 30**

| 14488M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *25.36 | 25.00 | [a] APO-Fluvoxamine [TX] | [a] Faverin 50 [RW] |
| | | | | | | [a] FLUVOXAMINE-WGR [WG] | [a] Movox 50 [AL] |
| | | | [B]6.78 | 32.14 | 25.00 | [a] Luvox [GO] | |

**fluvoxamine maleate 100 mg tablet, 30**

| 14314J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *30.98 | 25.00 | [a] APO-Fluvoxamine [TX] | [a] Faverin 100 [RW] |
| | | | | | | [a] FLUVOXAMINE-WGR [WG] | [a] Movox 100 [AF] |
| | | | [B]6.80 | 37.78 | 25.00 | [a] Luvox [GO] | |

## PAROXETINE

**Restricted benefit**

***4755***

Major depressive disorders

**Restricted benefit**

***6277***

Obsessive-compulsive disorder

**Restricted benefit**

***6636***

Panic disorder

**paroxetine 20 mg tablet, 30**

| 2242B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APX-Paroxetine [TY] | [a] Blooms The Chemist Paroxetine [BG] |
| | | | | | | [a] Extine 20 [RW] | [a] Paroxetine GH [GQ] |
| | | | | | | [a] Paroxetine Sandoz [SZ] | [a] PAROXETINE-WGR [WG] |
| | | | | | | [a] Paxtine [AF] | |
| | | | [B]2.41 | 20.51 | 19.64 | [a] Aropax [AS] | |

## PAROXETINE

**Restricted benefit**

***15666***

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

***15582***

Obsessive-compulsive disorder

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

***15722***

Panic disorder

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**paroxetine 20 mg tablet, 30**

| 14367E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *21.84 | 23.38 | [a] APX-Paroxetine [TY] | [a] Blooms The Chemist Paroxetine [BG] |
| | | | | | | [a] Extine 20 [RW] | [a] Paroxetine GH [GQ] |
| | | | | | | [a] Paroxetine Sandoz [SZ] | [a] PAROXETINE-WGR [WG] |
| | | | | | | [a] Paxtine [AF] | |
| | | | [B]4.82 | 26.66 | 23.38 | [a] Aropax [AS] | |

## SERTRALINE

**Restricted benefit**

***4755***

Major depressive disorders

**sertraline 50 mg tablet, 30**

| 2236Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Sertraline [TX] | [a] Blooms The Chemist Sertraline [BG] |
| | | | | | | [a] Eleva 50 [AF] | [a] Sertra 50 [RW] |
| | | | | | | [a] Sertraline generichealth [GQ] | [a] Sertraline Sandoz [SZ] |
| | | | | | | [a] SERTRALINE-WGR [WG] | [a] Setrona [RA] |
| | | | [B]6.47 | 23.57 | 18.64 | [a] Zoloft [GO] | |

**sertraline 100 mg tablet, 30**

| 2237R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Sertraline [TX] | [a] Blooms The Chemist Sertraline [BG] |
| | | | | | | [a] Eleva 100 [AF] | [a] Sertra 100 [RW] |
| | | | | | | [a] Sertraline generichealth [GQ] | [a] Sertraline Sandoz [SZ] |
| | | | | | | [a] SERTRALINE-WGR [WG] | [a] Setrona [RA] |
| | | | [B]6.47 | 23.57 | 18.64 | [a] Zoloft [GO] | |

## SERTRALINE

**Restricted benefit**

***15666***

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**sertraline 50 mg tablet, 30**

| 14400X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *19.84 | 21.38 | [a] APO-Sertraline [TX] | [a] Blooms The Chemist Sertraline [BG] |
| | | | | | | [a] Eleva 50 [AF] | [a] Sertra 50 [RW] |
| | | | | | | [a] Sertraline generichealth [GQ] | [a] Sertraline Sandoz [SZ] |
| | | | | | | [a] SERTRALINE-WGR [WG] | [a] Setrona [RA] |
| | | | [B]12.94 | 32.78 | 21.38 | [a] Zoloft [GO] | |

**sertraline 100 mg tablet, 30**

| 14506L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *19.84 | 21.38 | [a] APO-Sertraline [TX] | [a] Blooms The Chemist Sertraline [BG] |
| | | | | | | [a] Eleva 100 [AF] | [a] Sertra 100 [RW] |
| | | | | | | [a] Sertraline generichealth [GQ] | [a] Sertraline Sandoz [SZ] |
| | | | | | | [a] SERTRALINE-WGR [WG] | [a] Setrona [RA] |
| | | | [B]12.94 | 32.78 | 21.38 | [a] Zoloft [GO] | |

## SERTRALINE

**Restricted benefit**

***6277***

Obsessive-compulsive disorder

**Restricted benefit**

***6289***

Panic disorder

**Clinical criteria:**

- The treatment must be for use when other treatments have failed; **OR**
- The treatment must be for use when other treatments are inappropriate.

### sertraline 50 mg tablet, 30

| 8836C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Sertraline [TX] | [a] Blooms The Chemist Sertraline [BG] |
| | | | | | | [a] Eleva 50 [AF] | [a] Sertra 50 [RW] |
| | | | | | | [a] Sertraline generichealth [GQ] | [a] Sertraline Sandoz [SZ] |
| | | | | | | [a] SERTRALINE-WGR [WG] | |
| | | | [B]6.47 | 23.57 | 18.64 | [a] Zoloft [GO] | |

### sertraline 100 mg tablet, 30

| 8837D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 17.10 | 18.64 | [a] APO-Sertraline [TX] | [a] Blooms The Chemist Sertraline [BG] |
| | | | | | | [a] Eleva 100 [AF] | [a] Sertra 100 [RW] |
| | | | | | | [a] Sertraline generichealth [GQ] | [a] Sertraline Sandoz [SZ] |
| | | | | | | [a] SERTRALINE-WGR [WG] | |
| | | | [B]6.47 | 23.57 | 18.64 | [a] Zoloft [GO] | |

## SERTRALINE

**Restricted benefit**

***15582***

Obsessive-compulsive disorder

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Restricted benefit**

***15583***

Panic disorder

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for use when other treatments have failed; **OR**
- The treatment must be for use when other treatments are inappropriate.

### sertraline 50 mg tablet, 30

| 14403C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *19.84 | 21.38 | [a] APO-Sertraline [TX] | [a] Blooms The Chemist Sertraline [BG] |
| | | | | | | [a] Eleva 50 [AF] | [a] Sertra 50 [RW] |
| | | | | | | [a] Sertraline generichealth [GQ] | [a] Sertraline Sandoz [SZ] |
| | | | | | | [a] SERTRALINE-WGR [WG] | |
| | | | [B]12.94 | 32.78 | 21.38 | [a] Zoloft [GO] | |

### sertraline 100 mg tablet, 30

| 14404D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *19.84 | 21.38 | [a] APO-Sertraline [TX] | [a] Blooms The Chemist Sertraline [BG] |
| | | | | | | [a] Eleva 100 [AF] | [a] Sertra 100 [RW] |
| | | | | | | [a] Sertraline generichealth [GQ] | [a] Sertraline Sandoz [SZ] |
| | | | | | | [a] SERTRALINE-WGR [WG] | |
| | | | [B]12.94 | 32.78 | 21.38 | [a] Zoloft [GO] | |

## *Monoamine oxidase inhibitors, non-selective*

## PHENELZINE

**Caution** This drug is an irreversible monoamine oxidase inhibitor.

**Restricted benefit**

***6236***

Depression

**Clinical criteria:**

- The treatment must be for when all other anti-depressant therapy has failed; **OR**
- The treatment must be for when all other anti-depressant therapy is inappropriate.

**Caution** This drug is an irreversible monoamine oxidase inhibitor.

**phenelzine 15 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2856H | 1 | 1 | 0.00 | 215.41 | 25.00 | Nardil [NG] |

## TRANYLCYPROMINE

**Caution** This drug is an irreversible monoamine oxidase inhibitor.

**tranylcypromine 10 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2444P | 1 | 2 | 0.00 | 51.53 | 25.00 | [a] Parnate [GH] | [a] TRANYLMED [DZ] |

## TRANYLCYPROMINE

**Caution** This drug is an irreversible monoamine oxidase inhibitor.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**tranylcypromine 10 mg tablet, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14401Y | 2 | 1 | 0.00 | *88.70 | 25.00 | [a] Parnate [GH] | [a] TRANYLMED [DZ] |

### *Monoamine oxidase A inhibitors*

## MOCLOBEMIDE

**Restricted benefit**

***5650***

Major depressive disorders

**moclobemide 150 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1900B | | | | | | | |
| NP | 1 | 5 | 0.00 | 19.81 | 21.35 | [a] Amira 150 [AF] | [a] Clobemix [XT] |
| | | | | | | [a] Moclobemide Sandoz [SZ] | [a] MOCLOBEMIDE-WGR [WG] |
| | | | [B]3.86 | 23.67 | 21.35 | [a] Aurorix [GO] | |

**moclobemide 300 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8003F | | | | | | | |
| NP | 1 | 5 | 0.00 | 23.43 | 24.97 | [a] Amira 300 [AF] | [a] Clobemix [XT] |
| | | | | | | [a] Moclobemide Sandoz [SZ] | [a] MOCLOBEMIDE-WGR [WG] |
| | | | [B]3.88 | 27.31 | 24.97 | [a] Aurorix 300 mg [GO] | |

## MOCLOBEMIDE

**Restricted benefit**

***15553***

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**moclobemide 150 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14560H | | | | | | | |
| NP | 2 | 2 | 0.00 | *25.26 | 25.00 | [a] Amira 150 [AF] | [a] Clobemix [XT] |
| | | | | | | [a] Moclobemide Sandoz [SZ] | [a] MOCLOBEMIDE-WGR [WG] |
| | | | [B]7.72 | 32.98 | 25.00 | [a] Aurorix [GO] | |

**moclobemide 300 mg tablet, 60**

| 14442D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *32.50 | 25.00 | [a] Amira 300 [AF] | [a] Clobemix [XT] |
| | | | | | | [a] Moclobemide Sandoz [SZ] | [a] MOCLOBEMIDE-WGR [WG] |
| | | | [B]7.76 | 40.26 | 25.00 | [a] Aurorix 300 mg [GO] | |

## *Other antidepressants*

### DESVENLAFAXINE

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

**Restricted benefit**

***5650***

Major depressive disorders

**desvenlafaxine 50 mg modified release tablet, 28**

| 9366Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 4.37 | 25.46 | 22.63 | [a] Pristiq [PF] |

**desvenlafaxine 50 mg modified release tablet, 28**

| 10234P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.33 | 21.87 | [a] APO-Desvenlafaxine MR [TX] | [a] Desvenlafaxine GH XR [GQ] |

**desvenlafaxine 50 mg modified release tablet, 28**

| 10241B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.33 | 21.87 | [a] BTC Desvenlafaxine [BG] | [a] Desfax [AF] |
| | | | | | | [a] DESVEN [RW] | [a] Desvenlafaxine Sandoz [SZ] |
| | | | | | | [a] Desvenlafaxine Sandoz Pharma [HX] | [a] Desvenlafaxine Viatris [AL] |
| | | | | | | [a] DESVENLAFAXINE-WGR XR [WG] | |

### DESVENLAFAXINE

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

**Restricted benefit**

***5650***

Major depressive disorders

**desvenlafaxine 100 mg modified release tablet, 28**

| 9367B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 25.55 | 23.22 | [a] Pristiq [PF] |

**desvenlafaxine 100 mg modified release tablet, 28**

| 10231L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.68 | 23.22 | [a] BTC Desvenlafaxine [BG] | [a] Desfax [AF] |
| | | | | | | [a] DESVEN [RW] | [a] Desvenlafaxine Sandoz [SZ] |
| | | | | | | [a] Desvenlafaxine Sandoz Pharma [HX] | [a] Desvenlafaxine Viatris [AL] |
| | | | | | | [a] DESVENLAFAXINE-WGR XR [WG] | |

**desvenlafaxine 100 mg modified release tablet, 28**

| 10245F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 21.68 | 23.22 | [a] APO-Desvenlafaxine MR [TX] | [a] Desvenlafaxine GH XR [GQ] |

### DESVENLAFAXINE

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

**Restricted benefit**

***15553***

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**desvenlafaxine 50 mg modified release tablet, 28**

| 14383B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *26.30 | 25.00 | [a] BTC Desvenlafaxine [BG] | [a] Desfax [AF] |
| | | | | | | [a] DESVEN [RW] | [a] Desvenlafaxine Sandoz [SZ] |
| | | | | | | [a] Desvenlafaxine Sandoz Pharma [HX] | [a] Desvenlafaxine Viatris [AL] |
| | | | | | | [a] DESVENLAFAXINE-WGR XR [WG] | |

**desvenlafaxine 50 mg modified release tablet, 28**

| 14418W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *26.30 | 25.00 | [a] APO-Desvenlafaxine MR [TX] | [a] Desvenlafaxine GH XR [GQ] |

**desvenlafaxine 50 mg modified release tablet, 28**

| 14451N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 8.74 | *36.56 | 25.00 | [a] Pristiq [PF] |

## DESVENLAFAXINE

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

**Restricted benefit**

***15553***

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**desvenlafaxine 100 mg modified release tablet, 28**

| 14384C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *29.00 | 25.00 | [a] APO-Desvenlafaxine MR [TX] | [a] Desvenlafaxine GH XR [GQ] |

**desvenlafaxine 100 mg modified release tablet, 28**

| 14489N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *29.00 | 25.00 | [a] BTC Desvenlafaxine [BG] | [a] Desfax [AF] |
| | | | | | | [a] DESVEN [RW] | [a] Desvenlafaxine Sandoz [SZ] |
| | | | | | | [a] Desvenlafaxine Sandoz Pharma [HX] | [a] Desvenlafaxine Viatris [AL] |
| | | | | | | [a] DESVENLAFAXINE-WGR XR [WG] | |

**desvenlafaxine 100 mg modified release tablet, 28**

| 14545M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *36.74 | 25.00 | [a] Pristiq [PF] |

## DULOXETINE

**Restricted benefit**

***5650***

Major depressive disorders

**duloxetine 30 mg enteric capsule, 28**

| 9155W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 18.46 | 20.00 | [a] APO-Duloxetine [TX] | [a] Blooms The Chemist Duloxetine [BG] |
| | | | | | | [a] Duloxecor [CR] | [a] Duloxetine Sandoz [HX] |
| | | | | | | [a] Duloxetine Sandoz 30 [SZ] | [a] DULOXETINE-WGR [WG] |
| | | | | | | [a] DYTREX 30 [RW] | [a] Tixol 30 [AL] |

**duloxetine 60 mg enteric capsule, 28**

| 9156X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Duloxetine [TX] | [a] Blooms The Chemist Duloxetine [BG] |
| | | | | | | [a] Duloxecor [CR] | [a] Duloxetine Sandoz [HX] |
| | | | | | | [a] Duloxetine Sandoz 60 [SZ] | [a] DULOXETINE-WGR [WG] |

| 9156X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] DYTREX 60 [RW] | [a] Tixol 60 [AL] |

## DULOXETINE

**Restricted benefit**

***15553***

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### duloxetine 60 mg enteric capsule, 28

| 14712H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *22.84 | 24.38 | [a] APO-Duloxetine [TX] | [a] Blooms The Chemist Duloxetine [BG] |
| | | | | | | [a] Duloxecor [CR] | [a] Duloxetine Sandoz [HX] |
| | | | | | | [a] Duloxetine Sandoz 60 [SZ] | [a] DULOXETINE-WGR [WG] |
| | | | | | | [a] DYTREX 60 [RW] | [a] Tixol 60 [AL] |

## ESKETAMINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16454***

Treatment resistant major depression

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must have been inadequately responsive to at least two oral anti-depressant drug therapies.

**Treatment criteria:**

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The following must apply if reinitiating treatment:

(i) at least four-week gap from last treatment course to reinitiation of treatment; and

(ii) evidence, documented in the patient's medical record using a structured rating scale, of significant clinical therapeutic benefit of the prior course of treatment with esketamine; and

(iii) evidence, documented in the patient's medical record using a structured rating scale, of a relapse in depression.

The listed quantity of 24 units of nasal spray is intended for a dosage of 84 mg per treatment administration in the induction treatment setting.

### esketamine 28 mg/2 actuations nasal spray, 3 x 2 actuations

| 14786F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 8 | 0 | 0.00 | *7,478.57 | 25.00 | Spravato [JC] |

## ESKETAMINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16470***

Treatment resistant major depression

Treatment Phase: Non-induction treatment

**Clinical criteria:**

- The treatment must be to continue existing PBS-subsidised treatment for this indication, **AND**
- The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks, **AND**
- Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records).

**Treatment criteria:**

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**

- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The listed quantity of 8 units of nasal spray is intended for a dosage of 56 mg per treatment administration in the non-induction treatment setting.

**esketamine 28 mg/2 actuations nasal spray, 2 x 2 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14794P | 4 | 5 | 0.00 | *2,569.57 | 25.00 | Spravato [JC] |

## ESKETAMINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16460***

Treatment resistant major depression

Treatment Phase: Non-induction treatment

**Clinical criteria:**

- The treatment must be to continue existing PBS-subsidised treatment for this indication, **AND**
- The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks, **AND**
- Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records).

**Treatment criteria:**

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The listed quantity of 4 units of nasal spray is intended for a dosage of 28 mg per treatment administration in the non-induction treatment setting.

**esketamine 28 mg/2 actuations nasal spray, 2 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14812N | 4 | 5 | 0.00 | *1,303.69 | 25.00 | Spravato [JC] |

## ESKETAMINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16422***

Treatment resistant major depression

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must have been inadequately responsive to at least two oral anti-depressant drug therapies.

**Treatment criteria:**

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The following must apply if reinitiating treatment:

(i) at least four-week gap from last treatment course to reinitiation of treatment; and

(ii) evidence, documented in the patient's medical record using a structured rating scale, of significant clinical therapeutic benefit of the prior course of treatment with esketamine; and

(iii) evidence, documented in the patient's medical record using a structured rating scale, of a relapse in depression.

The listed quantity of 16 units of nasal spray is intended for a dosage of 56 mg per treatment administration in the induction treatment setting.

**esketamine 28 mg/2 actuations nasal spray, 2 x 2 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14815R | 8 | 0 | 0.00 | *5,024.09 | 25.00 | Spravato [JC] |

## ESKETAMINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**

***16419***

Treatment resistant major depression

Treatment Phase: Non-induction treatment

**Clinical criteria:**

- The treatment must be to continue existing PBS-subsidised treatment for this indication, **AND**
- The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks, **AND**
- Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records).

**Treatment criteria:**

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The listed quantity of 12 units of nasal spray is intended for a dosage of 84 mg per treatment administration in the non-induction treatment setting.

**esketamine 28 mg/2 actuations nasal spray, 3 x 2 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14830M | 4 | 5 | 0.00 | *3,796.81 | 25.00 | Spravato [JC] |

## ESKETAMINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**

***16477***

Treatment resistant major depression

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must have been inadequately responsive to at least two oral anti-depressant drug therapies.

**Treatment criteria:**

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The following must apply if reinitiating treatment:

(i) at least four-week gap from last treatment course to reinitiation of treatment; and

(ii) evidence, documented in the patient's medical record using a structured rating scale, of significant clinical therapeutic benefit of the prior course of treatment with esketamine; and

(iii) evidence, documented in the patient's medical record using a structured rating scale, of a relapse in depression.

The listed quantity of 8 units of nasal spray is intended for a dosage of 28 mg per treatment administration in the induction treatment setting.

**esketamine 28 mg/2 actuations nasal spray, 2 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14836W | 8 | 0 | 0.00 | *2,569.61 | 25.00 | Spravato [JC] |

## LITHIUM CARBONATE

**Restricted benefit**

***16559***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**lithium carbonate 250 mg tablet, 200**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3059B | 1 | 2 | 0.00 | 49.38 | 25.00 | Lithicarb [AS] |
| NP | | | | | | |

**lithium carbonate 450 mg modified release tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8290H | 2 | 2 | 0.00 | *79.98 | 25.00 | Quilonum SR [AS] |
| NP | | | | | | |

## MIANSERIN

**Caution** Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

**Restricted benefit**

***6278***

Severe depression

### mianserin hydrochloride 10 mg tablet, 50

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1627P | | | | | | |
| NP | 1 | 5 | 0.00 | 21.92 | 23.46 | Lumin 10 [AF] |

### mianserin hydrochloride 20 mg tablet, 50

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1628Q | | | | | | |
| NP | 1 | 5 | 0.00 | 30.32 | 25.00 | Lumin 20 [AF] |

## MIANSERIN

**Caution** Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

**Restricted benefit**

***15580***

Severe depression

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### mianserin hydrochloride 10 mg tablet, 50

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14366D | | | | | | |
| NP | 2 | 2 | 0.00 | *29.48 | 25.00 | Lumin 10 [AF] |

### mianserin hydrochloride 20 mg tablet, 50

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14505K | | | | | | |
| NP | 2 | 2 | 0.00 | *46.28 | 25.00 | Lumin 20 [AF] |

## MIRTAZAPINE

**Restricted benefit**

***5650***

Major depressive disorders

### mirtazapine 15 mg orally disintegrating tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8855C | | | | | | |
| NP | 1 | 5 | 0.00 | 18.45 | 19.99 | MIRTANZA ODT [RF] |

### mirtazapine 15 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9365X | | | | | | | |
| NP | 1 | 5 | 0.00 | 17.33 | 18.87 | [a] APX-Mirtazapine [TY] | [a] Axit 15 [AF] |
| | | | | | | [a] Blooms The Chemist Mirtazapine [BG] | [a] MIRTANZA [RF] |
| | | | | | | [a] Mirtazapine Sandoz [SZ] | [a] MIRTAZAPINE-WGR [WG] |

### mirtazapine 30 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8513C | | | | | | | |
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APX-Mirtazapine [TY] | [a] Axit 30 [AF] |
| | | | | | | [a] Blooms The Chemist Mirtazapine [BG] | [a] MIRTANZA [RF] |
| | | | | | | [a] Mirtazapine Sandoz [SZ] | [a] MIRTAZAPINE-WGR [WG] |
| | | | [B]5.74 | 23.84 | 19.64 | [a] Avanza [AL] | |

### mirtazapine 30 mg orally disintegrating tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8856D | | | | | | |
| NP | 1 | 5 | 0.00 | 18.97 | 20.51 | MIRTANZA ODT [RF] |

### mirtazapine 45 mg orally disintegrating tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8857E | | | | | | |
| NP | 1 | 5 | 0.00 | 21.22 | 22.76 | MIRTANZA ODT [RF] |

### mirtazapine 45 mg tablet, 30

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8883M | | | | | | | |
| NP | 1 | 5 | 0.00 | 19.35 | 20.89 | [a] APX-Mirtazapine [TY] | [a] Axit 45 [AF] |

| 8883M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | | | | | | [a] Blooms The Chemist Mirtazapine [BG] | [a] MIRTANZA [RF] |
| | | | | | | [a] Mirtazapine Sandoz [SZ] | [a] MIRTAZAPINE-WGR [WG] |

## MIRTAZAPINE

**Restricted benefit**

***15553***

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### mirtazapine 15 mg orally disintegrating tablet, 30

| 14369G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *22.54 | 24.08 | MIRTANZA ODT [RF] |

### mirtazapine 15 mg tablet, 30

| 14507M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *20.30 | 21.84 | [a] APX-Mirtazapine [TY] | [a] Axit 15 [AF] |
| | | | | | | [a] Blooms The Chemist Mirtazapine [BG] | [a] MIRTANZA [RF] |
| | | | | | | [a] Mirtazapine Sandoz [SZ] | [a] MIRTAZAPINE-WGR [WG] |

### mirtazapine 30 mg orally disintegrating tablet, 30

| 14370H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *23.58 | 25.00 | MIRTANZA ODT [RF] |

### mirtazapine 30 mg tablet, 30

| 14473R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *21.84 | 23.38 | [a] APX-Mirtazapine [TY] | [a] Axit 30 [AF] |
| | | | | | | [a] Blooms The Chemist Mirtazapine [BG] | [a] MIRTANZA [RF] |
| | | | | | | [a] Mirtazapine Sandoz [SZ] | [a] MIRTAZAPINE-WGR [WG] |
| | | | [B]11.48 | 33.32 | 23.38 | [a] Avanza [AL] | |

### mirtazapine 45 mg orally disintegrating tablet, 30

| 14475W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *28.08 | 25.00 | MIRTANZA ODT [RF] |

### mirtazapine 45 mg tablet, 30

| 14561J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *24.34 | 25.00 | [a] APX-Mirtazapine [TY] | [a] Axit 45 [AF] |
| | | | | | | [a] Blooms The Chemist Mirtazapine [BG] | [a] MIRTANZA [RF] |
| | | | | | | [a] Mirtazapine Sandoz [SZ] | [a] MIRTAZAPINE-WGR [WG] |

## REBOXETINE

**Restricted benefit**

***5650***

Major depressive disorders

### reboxetine 4 mg tablet, 60

| 8583R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 40.27 | 25.00 | Edronax [PF] |

## REBOXETINE

**Restricted benefit**

***15553***

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### reboxetine 4 mg tablet, 60

| 14474T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *66.18 | 25.00 | Edronax [PF] |

## VENLAFAXINE

**Restricted benefit**

***5650***

Major depressive disorders

### venlafaxine 37.5 mg modified release capsule, 28

| 8868R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 17.32 | 18.86 | [a] Efexor-XR [GO] | [a] Elaxine SR 37.5 [RW] |
| | | | | | | [a] VENLAFAXINE XR-WGR [WG] | |

### venlafaxine 75 mg modified release capsule, 28

| 8301X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.10 | 19.64 | [a] APO-Venlafaxine XR [TX] | [a] BTC Venlafaxine XR [BG] |
| | | | | | | [a] Elaxine SR 75 [RW] | [a] Enlafax-XR [AF] |
| | | | | | | [a] Sandoz Venlafaxine XR [HX] | [a] Venlafaxine generichealth XR [GQ] |
| | | | | | | [a] VENLAFAXINE XR-WGR [WG] | |
| | | | [B]2.00 | 20.10 | 19.64 | [a] Efexor-XR [GO] | |

### venlafaxine 150 mg modified release capsule, 28

| 8302Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Venlafaxine XR [TX] | [a] BTC Venlafaxine XR [BG] |
| | | | | | | [a] Elaxine SR 150 [RW] | [a] Enlafax-XR [AF] |
| | | | | | | [a] Sandoz Venlafaxine XR [HX] | [a] Venlafaxine generichealth XR [GQ] |
| | | | | | | [a] VENLAFAXINE XR-WGR [WG] | |
| | | | [B]1.93 | 20.53 | 20.14 | [a] Efexor-XR [GO] | |

## VENLAFAXINE

**Restricted benefit**

***15553***

Major depressive disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### venlafaxine 75 mg modified release capsule, 28

| 14472Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *21.84 | 23.38 | [a] APO-Venlafaxine XR [TX] | [a] BTC Venlafaxine XR [BG] |
| | | | | | | [a] Elaxine SR 75 [RW] | [a] Enlafax-XR [AF] |
| | | | | | | [a] Sandoz Venlafaxine XR [HX] | [a] Venlafaxine generichealth XR [GQ] |
| | | | | | | [a] VENLAFAXINE XR-WGR [WG] | |
| | | | [B]4.00 | 25.84 | 23.38 | [a] Efexor-XR [GO] | |

### venlafaxine 150 mg modified release capsule, 28

| 14402B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 2 | 0.00 | *22.84 | 24.38 | [a] APO-Venlafaxine XR [TX] | [a] BTC Venlafaxine XR [BG] |
| | | | | | | [a] Elaxine SR 150 [RW] | [a] Enlafax-XR [AF] |
| | | | | | | [a] Sandoz Venlafaxine XR [HX] | [a] Venlafaxine generichealth XR [GQ] |
| | | | | | | [a] VENLAFAXINE XR-WGR [WG] | |
| | | | [B]3.86 | 26.70 | 24.38 | [a] Efexor-XR [GO] | |

## PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS

## GUANFACINE

**Authority Required (STREAMLINED)**

***9034***

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatrician or psychiatrist.

**Clinical criteria:**

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; **OR**
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; **OR**
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; **OR**
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

**Authority Required (STREAMLINED)**

***9031***

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; **OR**
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; **OR**
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; **OR**
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Authority Required (STREAMLINED)**

***8544***

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatrician or psychiatrist.

**Clinical criteria:**

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must be receiving a maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine) which has been stable for at least four weeks, **AND**
- The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine), **AND**
- Patient must be experiencing residual moderate to severe ADHD symptoms resulting in impaired functioning (social, academic or occupational), present in at least one setting (home, nursery/school/college/work, friends or family homes or other environment).

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

**Authority Required (STREAMLINED)**

***8585***

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine).

### guanfacine 1 mg modified release tablet, 28

| 11452R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 39.50 | 25.00 | [a] Guanfacine MHC [XT] | [a] Guanfacine Sandoz [SZ] |
| | | | | | | [a] Guanfacine Viatris [AF] | [a] Intuniv [TK] |

### guanfacine 2 mg modified release tablet, 28

| 11451Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 39.50 | 25.00 | [a] Guanfacine MHC [XT] | [a] Guanfacine Sandoz [SZ] |
| | | | | | | [a] Guanfacine Viatris [AF] | [a] Intuniv [TK] |

**guanfacine 3 mg modified release tablet, 28**

| 11440D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 39.50 | 25.00 | [a] Guanfacine MHC [XT] | [a] Guanfacine Sandoz [SZ] |
| | | | | | | [a] Guanfacine Viatris [AF] | [a] Intuniv [TK] |

**guanfacine 4 mg modified release tablet, 28**

| 11441E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 39.50 | 25.00 | [a] Guanfacine MHC [XT] | [a] Guanfacine Sandoz [SZ] |
| | | | | | | [a] Guanfacine Viatris [AF] | [a] Intuniv [TK] |

## *Centrally acting sympathomimetics*

## ARMODAFINIL

**Note** This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamfetamine sulfate or modafinil.

**Authority Required**

***18333***

Narcolepsy

Treatment Phase: Initial 1 - treatment of narcolepsy without cataplexy

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; **OR**
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); **OR**
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

(a) details of the proposed prescription; and

(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and

(c) details of the contraindication or intolerance to dexamfetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***10935***

Narcolepsy

Treatment Phase: Initial 2 - treatment of narcolepsy with cataplexy

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; **OR**
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a definite history of cataplexy documented in their medical records for auditing purposes, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority Required**

***10967***

Narcolepsy

Treatment Phase: Continuing or change of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have previously received PBS-subsidised treatment with modafinil for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**armodafinil 50 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10922W | 2 | 5 | 0.00 | *101.76 | 25.00 | Nuvigil [FW] |

**armodafinil 150 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10912H | 1 | 5 | 0.00 | 147.00 | 25.00 | Nuvigil [FW] |

**armodafinil 250 mg tablet, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10919Q | 1 | 5 | 0.00 | 238.77 | 25.00 | Nuvigil [FW] |

## ATOMOXETINE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***7876***

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatrician or psychiatrist.

**Clinical criteria:**

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; **OR**
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; **OR**
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; **OR**
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Authority Required (STREAMLINED)**

***7890***

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**atomoxetine 10 mg capsule, 28**

| 9092M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *74.18 | 25.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

**atomoxetine 18 mg capsule, 28**

| 9093N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *74.18 | 25.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

**atomoxetine 25 mg capsule, 28**

| 9094P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *74.18 | 25.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

**atomoxetine 40 mg capsule, 28**

| 9095Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *74.18 | 25.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

**atomoxetine 60 mg capsule, 28**

| 9096R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *74.18 | 25.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

**atomoxetine 80 mg capsule, 28**

| 9289X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 53.25 | 25.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

**atomoxetine 100 mg capsule, 28**

| 9290Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 62.18 | 25.00 | [a] APO-Atomoxetine [TX] | [a] Atomoxetine Sandoz [SZ] |

## DEXAMFETAMINE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority Required**

***16596***

Attention deficit hyperactivity disorder

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

Treatment must be in accordance with the law of the relevant State or Territory.

**Authority Required**

***16629***

Narcolepsy

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**dexamfetamine sulfate 5 mg tablet, 100**

| 1165H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 26.30 | 25.00 | Aspen Pharmacare Australia Pty Ltd [AS] |

## LISDEXAMFETAMINE

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16597***

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must require continuous coverage over 12 hours, **AND**

- The treatment must not exceed a maximum daily dose of 70 mg of PBS-subsidised treatment with this drug.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive; **OR**
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; **OR**
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; **OR**
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party**,** has occurred and which supports point (i) above.

**lisdexamfetamine dimesilate 20 mg capsule, 30**

| 11884L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 46.10 | 25.00 | Vyvanse [TK] |

**lisdexamfetamine dimesilate 30 mg capsule, 30**

| 10486X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 46.10 | 25.00 | Vyvanse [TK] |

**lisdexamfetamine dimesilate 40 mg capsule, 30**

| 11898F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 46.10 | 25.00 | Vyvanse [TK] |

**lisdexamfetamine dimesilate 50 mg capsule, 30**

| 10474G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 46.10 | 25.00 | Vyvanse [TK] |

**lisdexamfetamine dimesilate 60 mg capsule, 30**

| 11897E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 46.10 | 25.00 | Vyvanse [TK] |

**lisdexamfetamine dimesilate 70 mg capsule, 30**

| 10492F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 46.10 | 25.00 | Vyvanse [TK] |

## METHYLPHENIDATE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Where an increase in maximum quantity is sought, under no circumstances will a quantity beyond 2 times the listed quantity be approved.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16596***

Attention deficit hyperactivity disorder

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

Treatment must be in accordance with the law of the relevant State or Territory.

**methylphenidate hydrochloride 10 mg tablet, 100**

| 8839F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 36.96 | 25.00 | [a] Artige [NM] | [a] Rinidate [NB] |
| | | | | | | [a] Ritalin 10 [NV] | |

## METHYLPHENIDATE

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16545***

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg of PBS-subsidised treatment with this drug.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive; **OR**
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; **OR**
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; **OR**
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party**,** has occurred and which supports point (i) above.

**methylphenidate hydrochloride 40 mg modified release capsule, 30**

| 2283E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 55.30 | 25.00 | [a] ATTORA LA [XT]<br>[a] Rubifen LA [AE] | [a] Ritalin LA [NV] |

## METHYLPHENIDATE

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16545***

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg of PBS-subsidised treatment with this drug.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive; **OR**
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; **OR**
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; **OR**
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party**,** has occurred and which supports point (i) above.

**methylphenidate hydrochloride 10 mg modified release capsule, 30**

| 3440C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 38.73 | 25.00 | [a] ATTORA LA [XT] | [a] Ritalin LA [NV] |
| | | | | | | [a] Rubifen LA [AE] | |

**methylphenidate hydrochloride 20 mg modified release capsule, 30**

| 2276T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 46.71 | 25.00 | [a] ATTORA LA [XT] | [a] Ritalin LA [NV] |
| | | | | | | [a] Rubifen LA [AE] | |

**methylphenidate hydrochloride 30 mg modified release capsule, 30**

| 2280B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 53.11 | 25.00 | [a] ATTORA LA [XT] | [a] Ritalin LA [NV] |
| | | | | | | [a] Rubifen LA [AE] | |

## METHYLPHENIDATE

**Note** Pharmaceutical benefits that have the form methylphenidate hydrochloride modified release tablet can be substituted for Concerta (Switzerland) in the case of a shortage

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16598***

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg of PBS-subsidised treatment with this drug.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**methylphenidate hydrochloride 36 mg modified release tablet, 30**

| 2388Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 59.63 | 25.00 | [a] Concerta [JC] | [a] Methylphenidate Sandoz XR [SZ] |
| | | | | | | [a] METHYLPHENIDATE-TEVA XR [TB] | [a] Methylphenidate XR ARX [XT] |

**methylphenidate hydrochloride 36 mg modified release tablet, 60**

| 14862F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 0.5 | 5 | 0.00 | *192.40 | 25.00 | [a] Concerta (Switzerland) [DZ] |

## METHYLPHENIDATE

**Note** Pharmaceutical benefits that have the form methylphenidate hydrochloride modified release tablet can be substituted for Concerta (Switzerland) or Atenza (Spain) in the case of a shortage

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16598***

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg of PBS-subsidised treatment with this drug.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**methylphenidate hydrochloride 27 mg modified release tablet, 30**

| 2172H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 56.06 | 25.00 | [a] Concerta [JC] | [a] Methylphenidate Sandoz XR [SZ] |
| | | | | | | [a] METHYLPHENIDATE-TEVA XR [TB] | [a] Methylphenidate XR ARX [XT] |

**methylphenidate hydrochloride 54 mg modified release tablet, 30**

| 2432B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 67.49 | 25.00 | [a] Concerta [JC] | [a] Methylphenidate Sandoz XR [SZ] |
| | | | | | | [a] METHYLPHENIDATE-TEVA XR [TB] | [a] Methylphenidate XR ARX [XT] |

**methylphenidate hydrochloride 54 mg modified release tablet, 60**

| 14871Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 0.5 | 5 | 0.00 | *220.13 | 25.00 | [a] Concerta (Switzerland) [DZ] |

## METHYLPHENIDATE

**Note** Pharmaceutical benefits that have the form methylphenidate hydrochloride modified release tablet can be substituted for Concerta (Switzerland) in the case of a shortage
**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength
**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.
**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16598***

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg of PBS-subsidised treatment with this drug.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

**methylphenidate hydrochloride 18 mg modified release tablet, 30**

| 2387P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 52.51 | 25.00 | [a] Concerta [JC] | [a] Methylphenidate Sandoz XR [SZ] |
| | | | | | | [a] METHYLPHENIDATE-TEVA XR [TB] | [a] Methylphenidate XR ARX [XT] |

**methylphenidate hydrochloride 18 mg modified release tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14857Y NP | 0.5 | 5 | 0.00 | *149.67 | 25.00 | [a] Concerta (Switzerland) [DZ] |

## METHYLPHENIDATE

**Note** Pharmaceutical benefits that have the brand Methylphenidate Orifarm 60 mg (Sweden) can be substituted for Attora LA, Ritalin LA or Rubifen LA in the case of a shortage.

**Note** In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

**Note** A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***16545***

Attention deficit hyperactivity disorder

**Clinical criteria:**

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg of PBS-subsidised treatment with this drug.

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive; **OR**
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; **OR**
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; **OR**
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party**,** has occurred and which supports point (i) above.

**methylphenidate hydrochloride 60 mg modified release capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12116Q NP | 1 | 5 | 0.00 | 67.26 | 25.00 | [a] ATTORA LA [XT]<br>[a] Rubifen LA [AE] | [a] Ritalin LA [NV] |

## MODAFINIL

**Note** This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamfetamine sulfate or armodafinil.

**Authority Required**

***18333***

Narcolepsy

Treatment Phase: Initial 1 - treatment of narcolepsy without cataplexy

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; **OR**
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); **OR**
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

(a) details of the proposed prescription; and

(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and

(c) details of the contraindication or intolerance to dexamfetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***10935***

Narcolepsy

Treatment Phase: Initial 2 - treatment of narcolepsy with cataplexy

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; **OR**
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a definite history of cataplexy documented in their medical records for auditing purposes, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority Required**

***10968***

Narcolepsy

Treatment Phase: Continuing or change of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have previously received PBS-subsidised treatment with armodafinil for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**modafinil 100 mg tablet, 60**

| 8816B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *115.30 | 25.00 | [a] APO-Modafinil [TX] | [a] Modafin [RW] |
| | | | | | | [a] Modafinil GH [GQ] | [a] Modafinil Sandoz [SZ] |
| | | | | | | [a] Modafinil Viatris [AL] | [a] MODAFINIL-WGR [WG] |
| | | | [B]9.12 | 124.42 | 25.00 | [a] Modavigil [FW] | |

## ANTI-DEMENTIA DRUGS

### *Anticholinesterases*

## DONEPEZIL

**Authority Required (STREAMLINED)**

***13938***

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**donepezil hydrochloride 5 mg tablet, 28**

| 2532G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.70 | 20.24 | [a] APO-Donepezil [TX] | [a] Arazil [AF] |
| | | | | | | [a] Aridon 5 [RW] | [a] Aridon APN 5 [RF] |
| | | | | | | [a] Donepezil GH [HQ] | [a] Donepezil Sandoz [SZ] |
| | | | | | | [a] DONEPEZIL-WGR [WG] | |
| | | | [B]4.40 | 23.10 | 20.24 | [a] Aricept [PF] | |

**donepezil hydrochloride 10 mg tablet, 28**

| 2479L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.70 | 20.24 | [a] APO-Donepezil [TX] | [a] Arazil [AF] |
| | | | | | | [a] Aridon 10 [RW] | [a] Aridon APN 10 [RF] |
| | | | | | | [a] Donepezil GH [HQ] | [a] Donepezil Sandoz [SZ] |
| | | | | | | [a] DONEPEZIL-WGR [WG] | |
| | | | [B]4.37 | 23.07 | 20.24 | [a] Aricept [PF] | |

## DONEPEZIL

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***13941***

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**Authority Required**

***13940***

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**donepezil hydrochloride 5 mg tablet, 28**

| 8495D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.70 | 20.24 | [a] APO-Donepezil [TX] | [a] Arazil [AF] |
| | | | | | | [a] Aridon 5 [RW] | [a] Aridon APN 5 [RF] |
| | | | | | | [a] Donepezil GH [HQ] | [a] Donepezil Sandoz [SZ] |
| | | | | | | [a] DONEPEZIL-WGR [WG] | |
| | | | [B]4.40 | 23.10 | 20.24 | [a] Aricept [PF] | |

**donepezil hydrochloride 10 mg tablet, 28**

| 8496E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.70 | 20.24 | [a] APO-Donepezil [TX] | [a] Arazil [AF] |
| | | | | | | [a] Aridon 10 [RW] | [a] Aridon APN 10 [RF] |
| | | | | | | [a] Donepezil GH [HQ] | [a] Donepezil Sandoz [SZ] |
| | | | | | | [a] DONEPEZIL-WGR [WG] | |
| | | | [B]4.37 | 23.07 | 20.24 | [a] Aricept [PF] | |

## GALANTAMINE

**Authority Required (STREAMLINED)**

***13938***

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**galantamine 8 mg modified release capsule, 28**

| 2463P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 35.59 | 25.00 | [a] APO-Galantamine MR [TX] | [a] Galantyl [AF] |
| | | | | | | [a] Gamine XR [RW] | [a] Reminyl [IX] |

**galantamine 16 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2537M | | | | | | | |
| NP | 1 | 5 | 0.00 | 40.32 | 25.00 | [a] APO-Galantamine MR [TX] | [a] Galantyl [AF] |
| | | | | | | [a] Gamine XR [RW] | [a] Reminyl [IX] |

**galantamine 24 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2531F | | | | | | | |
| NP | 1 | 5 | 0.00 | 45.30 | 25.00 | [a] APO-Galantamine MR [TX] | [a] Galantyl [AF] |
| | | | | | | [a] Gamine XR [RW] | [a] Reminyl [IX] |

## GALANTAMINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***13941***

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**Authority Required**

***13940***

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**galantamine 8 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8770N | | | | | | | |
| NP | 1 | 5 | 0.00 | 35.59 | 25.00 | [a] APO-Galantamine MR [TX] | [a] Galantyl [AF] |
| | | | | | | [a] Gamine XR [RW] | [a] Reminyl [IX] |

**galantamine 16 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8771P | | | | | | | |
| NP | 1 | 5 | 0.00 | 40.32 | 25.00 | [a] APO-Galantamine MR [TX] | [a] Galantyl [AF] |
| | | | | | | [a] Gamine XR [RW] | [a] Reminyl [IX] |

**galantamine 24 mg modified release capsule, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8772Q | | | | | | | |
| NP | 1 | 5 | 0.00 | 45.30 | 25.00 | [a] APO-Galantamine MR [TX] | [a] Galantyl [AF] |
| | | | | | | [a] Gamine XR [RW] | [a] Reminyl [IX] |

## RIVASTIGMINE

**Authority Required (STREAMLINED)**

***13938***

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**rivastigmine 1.5 mg capsule, 56**

| 2475G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon [NV] |

**rivastigmine 3 mg capsule, 56**

| 2493F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon [NV] |

**rivastigmine 4.5 mg capsule, 56**

| 2494G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon [NV] |

**rivastigmine 4.6 mg/24 hours patch, 30**

| 2477J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon Patch 5 [NV] |

**rivastigmine 6 mg capsule, 56**

| 2526Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon [NV] |

**rivastigmine 9.5 mg/24 hours patch, 30**

| 2551G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon Patch 10 [NV] |

**rivastigmine 13.3 mg/24 hours patch, 30**

| 10538P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon Patch 15 [NV] |

## RIVASTIGMINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***13941***

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**Authority Required**

***13940***

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**rivastigmine 1.5 mg capsule, 56**

| 8497F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon [NV] |

**rivastigmine 3 mg capsule, 56**

| 8498G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon [NV] |

**rivastigmine 4.5 mg capsule, 56**

| 8499H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon [NV] |

**rivastigmine 4.6 mg/24 hours patch, 30**

| 9161E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon Patch 5 [NV] |

**rivastigmine 6 mg capsule, 56**

| 8500J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon [NV] |

**rivastigmine 9.5 mg/24 hours patch, 30**

| 9162F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon Patch 10 [NV] |

**rivastigmine 13.3 mg/24 hours patch, 30**

| 10541T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 81.78 | 25.00 | Exelon Patch 15 [NV] |

### *Other anti-dementia drugs*

## MEMANTINE

**Authority Required (STREAMLINED)**

***13966***

Moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
- Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**memantine hydrochloride 10 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2492E NP | 1 | 5 | 0.00 | 43.66 | 25.00 | [a] APO-Memantine [TX]<br>[a] Memantine generichealth [GQ] | [a] Ebixa [LU]<br>[a] Memanxa [RW] |

**memantine hydrochloride 20 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2513G NP | 1 | 5 | 0.00 | 43.66 | 25.00 | [a] APO-Memantine [TX]<br>[a] Memantine generichealth [GQ] | [a] Ebixa [LU] |

## MEMANTINE

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***14000***

Moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**Authority Required**

***13936***

Moderately severe Alzheimer disease

Treatment Phase: Initial

**Clinical criteria:**

- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

**memantine hydrochloride 10 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1956Y NP | 1 | 5 | 0.00 | 43.66 | 25.00 | [a] APO-Memantine [TX]<br>[a] Memantine generichealth [GQ] | [a] Ebixa [LU]<br>[a] Memanxa [RW] |

**memantine hydrochloride 20 mg tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 9306T NP | 1 | 5 | 0.00 | 43.66 | 25.00 | [a] APO-Memantine [TX]<br>[a] Memantine generichealth [GQ] | [a] Ebixa [LU] |

# OTHER NERVOUS SYSTEM DRUGS

## PARASYMPATHOMIMETICS

### *Anticholinesterases*

### PYRIDOSTIGMINE

**pyridostigmine bromide 10 mg tablet, 50**

| 2724J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *26.88 | 25.00 | Mestinon [IL] |

**pyridostigmine bromide 60 mg tablet, 150**

| 1959D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 50.52 | 25.00 | Mestinon [IL] |

**pyridostigmine bromide 180 mg modified release tablet, 50**

| 2608G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *93.92 | 25.00 | Mestinon Timespan [IL] |

### PYRIDOSTIGMINE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**pyridostigmine bromide 10 mg tablet, 50**

| 14392L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 5 | 0.00 | *39.40 | 25.00 | Mestinon [IL] |

**pyridostigmine bromide 60 mg tablet, 150**

| 14529Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 2 | 5 | 0.00 | *86.68 | 25.00 | Mestinon [IL] |

**pyridostigmine bromide 180 mg modified release tablet, 50**

| 14462E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 4 | 5 | 0.00 | *176.44 | 25.00 | Mestinon Timespan [IL] |

## DRUGS USED IN ADDICTIVE DISORDERS

### *Drugs used in nicotine dependence*

### BUPROPION

**Authority Required (STREAMLINED)**

***6882***

Nicotine dependence

Treatment Phase: Commencement of a short-term (9 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**Note** Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

**Note** The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**bupropion hydrochloride 150 mg modified release tablet, 30**

| 8465M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 64.26 | 25.00 | Zyban [AS] |

### BUPROPION

**Authority Required (STREAMLINED)**

***6881***
Nicotine dependence
Treatment Phase: Completion of a short-term (9 weeks) course of treatment
**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**Note** Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.
**Note** The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

### bupropion hydrochloride 150 mg modified release tablet, 90

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8710K NP | 1 | 0 | 0.00 | 166.53 | 25.00 | Zyban [AS] |

## NICOTINE

**Restricted benefit**
***5140***
Nicotine dependence
**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.
Benefit is improved if used in conjunction with a comprehensive support and counselling program.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

### nicotine 21 mg/24 hours patch, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5571F NP | 1 | 2 | 0.00 | 51.10 | 25.00 | Nicotinell Step 1 [UI] |

## NICOTINE

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**
***14040***
Nicotine dependence
**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must not be a PBS-benefit with other non-nicotine drugs that are PBS indicated for smoking cessation, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 2 x 12-week PBS-subsidised treatment courses per 12 month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

### nicotine 7 mg/24 hours patch, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5573H NP | 1 | 2 | 0.00 | 51.10 | 25.00 | Nicotinell Step 3 [UI] |

### nicotine 14 mg/24 hours patch, 28

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5572G NP | 1 | 2 | 0.00 | 51.10 | 25.00 | Nicotinell Step 2 [UI] |

**nicotine 21 mg/24 hours patch, 28**

| 3414Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 51.10 | 25.00 | Nicotinell Step 1 [UI] |

**nicotine 21 mg/24 hours patch, 28**

| 5465P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 51.10 | 25.00 | Nicabate P [RZ] |

**nicotine 25 mg/16 hours patch, 28**

| 10076H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 51.10 | 25.00 | nicorette 16hr Invisipatch [JT] |

## VARENICLINE

**Authority Required (STREAMLINED)**

***6885***

Nicotine dependence

Treatment Phase: Completion of a short-term (24 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**varenicline 1 mg tablet, 56**

| 5469W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 70.12 | 25.00 | [a] PHARMACOR VARENICLINE [CR] | [a] VARENAPIX [TX] |
| | | | | | | [a] Varenicline Lupin [GQ] | [a] Varenicline Sandoz [SZ] |
| | | | | | | [a] Varenicline Viatris [AF] | [a] VASSIX [NB] |

## VARENICLINE

**Authority Required (STREAMLINED)**

***6871***

Nicotine dependence

Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**varenicline 500 microgram tablet [11] (&) varenicline 1 mg tablet [42], 53**

| 9128K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 61.66 | 25.00 | [a] PHARMACOR VARENICLINE [CR] | [a] VARENAPIX [TX] |
| | | | | | | [a] Varenicline Lupin [GQ] | [a] Varenicline Sandoz [SZ] |
| | | | | | | [a] Varenicline Viatris [AF] | [a] VASSIX [NB] |

## VARENICLINE

**Authority Required (STREAMLINED)**

***7483***

Nicotine dependence

Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received treatment with this drug during this current course of treatment.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**varenicline 1 mg tablet, 56**

| 9129L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *126.46 | 25.00 | [a] PHARMACOR VARENICLINE [CR] | [a] VARENAPIX [TX] |
| | | | | | | [a] Varenicline Lupin [GQ] | [a] Varenicline Sandoz [SZ] |
| | | | | | | [a] Varenicline Viatris [AF] | [a] VASSIX [NB] |

### *Drugs used in alcohol dependence*

## ACAMPROSATE

**Authority Required (STREAMLINED)**

***5366***

Alcohol dependence

**Clinical criteria:**

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**acamprosate calcium 333 mg enteric tablet, 180**

| 8357W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 78.18 | 25.00 | [a] ACAMPROSATE VIATRIS [MQ] | [a] ACAMPROSATE-WGR [WG] |
| | | | | | | [a] APO-Acamprosate [TX] | [a] Campral [AF] |

## NALTREXONE

**Caution** Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***13967***

Alcohol dependence

**Clinical criteria:**

- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence/controlled consumption.

**naltrexone hydrochloride 50 mg tablet, 30**

| 8370M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 94.34 | 25.00 | [a] ARX-NALTREXONE [XT] | [a] Naltrexone GH [GQ] |

### OTHER NERVOUS SYSTEM DRUGS

## *Other nervous system drugs*

### AMIFAMPRIDINE

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***12979***

Lambert-Eaton myasthenic syndrome (LEMS)

**Clinical criteria:**

- The condition must not be any of: (i) myasthenia gravis, (ii) Guillain-Barre syndrome.

**Treatment criteria:**

- Must be treated by a prescriber type identifying as at least one of the following: (i) a clinical immunologist, (ii) a neurologist, (iii) a medical practitioner working under the direct supervision of one of these mentioned specialists.

**amifampridine 10 mg tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13032X | 2 | 5 | 0.00 | *5,703.26 | 25.00 | Ruzurgi [LD] |

### RILUZOLE

**Authority Required**

***15719***

Amyotrophic lateral sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be ambulatory; **OR**
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

**riluzole 50 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14393M NP | 2 | 5 | 0.00 | *204.38 | 25.00 | [a] Pharmacor Riluzole [CR]<br>[a] Riluzole Sandoz [SZ] | [a] Rilutek [SW] |

**riluzole 50 mg/10 mL oral liquid, 300 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14429K NP | 4 | 5 | 0.00 | *391.72 | 25.00 | Teglutik [JW] |

### RILUZOLE

**Authority Required**

***5341***

Amyotrophic lateral sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed by a neurologist, **AND**
- Patient must not have had the disease for more than 5 years, **AND**
- Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug, **AND**
- Patient must be ambulatory; **OR**
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

**Authority Required**

***8738***

Amyotrophic lateral sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be ambulatory; **OR**

- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

**riluzole 50 mg tablet, 56**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8664B NP | 1 | 5 | 0.00 | 107.23 | 25.00 | [a] Pharmacor Riluzole [CR]<br>[a] Riluzole Sandoz [SZ] | [a] Rilutek [SW] |

**riluzole 50 mg/10 mL oral liquid, 300 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11662T NP | 2 | 5 | 0.00 | *200.54 | 25.00 | Teglutik [JW] |

## TAFAMIDIS

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority Required**

***18247***

Transthyretin amyloid cardiomyopathy

Treatment Phase: First PBS-subsidised prescription for this drug

**Clinical criteria:**

- The condition must have documented evidence of transthyretin precursor protein present, **AND**
- Patient must have experienced at least one episode of hospitalisation that was a direct result of heart failure; **OR**
- Patient must have clinical evidence of heart failure without hospitalisation that required treatment with a diuretic for improvement, **AND**
- Patient must have/have had New York Heart Association class I heart failure at the time of commencing this drug; **OR**
- Patient must have/have had New York Heart Association class II heart failure at the time of commencing this drug, **AND**
- Patient must have an end-diastolic interventricular septal wall thickness of at least 12 mm on imaging, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 $m^2$.

**Treatment criteria:**

- Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of clinical findings to establish the diagnosis:

In this authority application, confirm that there is documented evidence of transthyretin precursor protein through either (1) alone, or, both (2) and (3), from the list below:

Confirm the following has been completed:

(1) amyloid expert centre histology findings derived via immunohistochemistry or mass spectrometry; OR

(2) bone scintigraphy with grade 2-3 finding

AND

(3) Confirm that there are negative results for monoclonal protein on each of the following three tests:

(a) serum immunofixation (also known as protein electrophoresis)

(b) urine immunofixation

(c) serum free light chains blood test

State which of (1) to (3) above has been completed, as well as the:

(i) date of the finding,

(ii) imaging/pathology report number/code that links the finding to the patient,

(iii) name of the amyloid expert centre in this authority application (if applicable).

For end-diastolic interventricular septal wall thickness (at least 12 mm), confirm that:

(i) imaging (echocardiogram or magnetic resonance imaging) has been undertaken; and

(ii) that the imaging report is stored in the patient's medical records.

State the date that the imaging was performed and the thickness (in mm) in this authority application.

Where this authority application is to transition a patient from non-PBS-subsidised to PBS-subsidised supply (i.e. a 'grandfathered' patient), confirm the following:

(i) the patient's heart failure has not worsened to persistent New York Heart Association Class III/IV heart failure while taking this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** The Australian Amyloid Network provides a list of clinic centres that manage amyloidosis. It also provides a list of Australian anatomical pathology laboratories to be contacted for tissue review and immunohistochemistry for amyloid typing. For the purposes of this restriction, these providers are considered to be amyloid expert centres.

**Authority Required**

***15303***

Transthyretin amyloid cardiomyopathy

Treatment Phase: Second and subsequent PBS-subsidised prescriptions for this drug

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 $m^2$, **AND**
- The treatment must be ceased where the patient's heart failure has worsened to persistent New York Heart Association (NYHA) Class III/IV heart failure, **AND**
- The treatment must be ceased where the patient has received any of: (i) a heart transplant, (ii) a liver transplant, (iii) an implanted ventricular assist device.

**Treatment criteria:**

- Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment.

Confirm whether heart failure has worsened to NYHA Class III/IV since the last authority application (yes/no).

If 'no', continued PBS subsidy is available.

If 'yes', continued PBS subsidy is available, but the prescriber must undertake a review of the patient within 3 months to determine whether the worsening heart failure was transient or persistent.

Where this subsequent clinical review finds that the heart failure persists as NYHA Class III/IV heart failure despite active treatment with this drug, then PBS subsidy is not available.

If heart failure has worsened to NYHA Class III/IV since the last authority application, no more than 2 repeat prescriptions must be prescribed.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tafamidis 61 mg capsule, 30**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14100D | 1 | 5 | 0.00 | 10,189.56 | 25.00 | Vyndamax [PF] |

## TETRABENAZINE

**Authority Required (STREAMLINED)**

***16537***

Hyperkinetic extrapyramidal disorders

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**tetrabenazine 25 mg tablet, 112**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1330B NP | 1 | 5 | 0.00 | 205.93 | 25.00 | [a] iNova Pharmaceuticals (Australia) Pty Ltd [IL] | [a] Tetrabenazine SUN [RA] |

## TETRABENAZINE

**Authority Required (STREAMLINED)**

***16699***

Hyperkinetic extrapyramidal disorders

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

**tetrabenazine 25 mg tablet, 112**

| 14390J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *402.50 | 25.00 | [a] iNova Pharmaceuticals (Australia) Pty Ltd [IL] | [a] Tetrabenazine SUN [RA] |

# ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

## ANTIPROTOZOALS

### AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES

#### *Other agents against amoebiasis and other protozoal diseases*

### ATOVAQUONE

**Authority Required (STREAMLINED)**

***5609***

Mild to moderate Pneumocystis carinii pneumonia

**Population criteria:**

- Patient must be an adult
- Patient must be intolerant of trimethoprim/sulfamethoxazole therapy.

**atovaquone 750 mg/5 mL oral liquid, 210 mL**

| 8300W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 0 | 0.00 | 631.63 | 25.00 | [a] ATOVACUE [JM] | [a] Wellvone [AS] |

### ANTIMALARIALS

#### *Biguanides*

### ATOVAQUONE + PROGUANIL

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**

***5981***

Confirmed or suspected Plasmodium falciparum malaria

**Population criteria:**

- Patient must be aged 3 years or older.

**Clinical criteria:**

- The treatment must be used where quinine containing regimens are inappropriate.

**atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12**

| 9439T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 55.81 | 25.00 | [a] AtovaquoPro Lupin 250/100 [GQ] | [a] Malarone [GK] |

#### *Methanolquinolines*

### QUININE

**Caution** Severe thrombocytopenia has been reported with this drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***18962***

Malaria

**Caution** Severe thrombocytopenia has been reported with this drug.

**quinine sulfate dihydrate 300 mg tablet, 50**

| 1975Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 2 | 0.00 | 24.06 | 25.00 | Quinate [RW] |

#### *Artemisinin and derivatives, combinations*

### ARTEMETHER + LUMEFANTRINE

**Restricted benefit**

***5999***

Confirmed or suspected Plasmodium falciparum malaria

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**artemether 20 mg + lumefantrine 120 mg tablet, 24**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9498X | 1 | 0 | 0.00 | 64.78 | 25.00 | Riamet [NV] |

# ANTHELMINTICS

## ANTITREMATODALS

### *Quinoline derivatives and related substances*

### PRAZIQUANTEL

**Note** Pharmaceutical benefits that have the brand Praziquantel tablets, USP 600 mg (Endo, USA) can be substituted for pharmaceutical benefits that have the brand Distocide (Korea) in the case of a shortage.

**Authority Required (STREAMLINED)**
***5659***
Schistosomiasis

**Praziquantel 600 mg tablet, 6**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15199Y NP | 1 | 0 | 0.00 | 885.48 | 25.00 | [a] Praziquantel Tablets, USP 600 mg (Endo, USA) [QY] |

**praziquantel 600 mg tablet, 8**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15239C NP | 0.75 | 0 | 0.00 | *139.81 | 25.00 | [a] Distocide (Korea) [LM] |

## ANTINEMATODAL AGENTS

### *Benzimidazole derivatives*

### ALBENDAZOLE

**Authority Required (STREAMLINED)**
***5680***
Tapeworm infestation

**albendazole 200 mg tablet, 6**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8503M NP | 1 | 1 | 0.00 | 29.62 | 25.00 | Zentel [AS] |

### ALBENDAZOLE

**Note** Pharmaceutical benefits that have the brand Albendazole (Micro Labs, Germany) may be substituted for pharmaceutical benefits that have the brand Eskazole in the case of a shortage.

**Authority Required (STREAMLINED)**
***5607***
Hydatid disease
**Clinical criteria:**

- The treatment must be in conjunction with surgery; **OR**
- The treatment must be used when a surgical cure cannot be achieved; **OR**
- The treatment must be used when surgery cannot be used.

**albendazole 400 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8459F | 1 | 2 | 0.00 | 114.00 | 25.00 | [a] Eskazole [AS] |

**albendazole 400 mg tablet, 60**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15560Y | 1 | 2 | 0.00 | 665.21 | 25.00 | [a] Albendazole (Micro Labs, Germany) [DZ] |

### ALBENDAZOLE

**Authority Required (STREAMLINED)**
***5817***
Whipworm infestation
**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority Required (STREAMLINED)**
***5712***
Strongyloidiasis
**Authority Required (STREAMLINED)**

***5797***
Hookworm infestation

**albendazole 200 mg tablet, 6**

| 9047E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 29.62 | 25.00 | Zentel [AS] |

## *Tetrahydropyrimidine derivatives*

## PYRANTEL

**pyrantel 125 mg tablet, 6**

| 3047J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 18.78 | 20.32 | Anthel 125 [AF] |

**pyrantel 250 mg tablet, 6**

| 3048K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 23.08 | 24.62 | Anthel 250 [AF] |

## *Avermectines*

## IVERMECTIN

**Authority Required (STREAMLINED)**
***4319***
Onchocerciasis

**ivermectin 3 mg tablet, 4**

| 8359Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 31.41 | 25.00 | [a] GLENMECT [JM] | [a] Stromectol [MK] |

## IVERMECTIN

**Authority Required (STREAMLINED)**
***4328***
Strongyloidiasis
**Authority Required (STREAMLINED)**
***4565***
Crusted (Norwegian) scabies
**Clinical criteria:**

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must be undergoing topical therapy for this condition; **OR**
- Patient must have a contraindication to topical treatment.

**Population criteria:**

- Patient must weigh 15 kg or over
- Patient must be 5 years of age or older.

**Authority Required (STREAMLINED)**
***4566***
Human sarcoptic scabies
**Clinical criteria:**

- The condition must be established by clinical and/or parasitological examination, **AND**
- Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; **OR**
- Patient must have a contraindication to topical treatment.

**Population criteria:**

- Patient must weigh 15 kg or over
- Patient must be 5 years of age or older.

**Note** This drug is not PBS-subsidised for first line treatment of typical scabies.

**Authority Required (STREAMLINED)**
***12604***
Human sarcoptic scabies
**Clinical criteria:**

- The condition must be established by clinical and/or parasitological examination.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander
- Patient must weigh 15 kg or over
- Patient must be 5 years of age or older.

**ivermectin 3 mg tablet, 4**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2868Y NP | 2 | 2 | 0.00 | *48.46 | 25.00 | [a] GLENMECT [JM] | [a] Stromectol [MK] |

# ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

## ECTOPARASITICIDES, INCL. SCABICIDES

### *Pyrethrines, incl. synthetic compounds*

### PERMETHRIN

**permethrin 5% cream, 30 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3054R NP | ‡1 | 1 | 0.00 | 23.09 | 24.63 | Lyclear [UI] |

# RESPIRATORY SYSTEM

## NASAL PREPARATIONS

## DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

### *Other nasal preparations*

### MUPIROCIN

**Authority Required (STREAMLINED)**

***6647***

Staphylococcus aureus infection

**Clinical criteria:**

- Patient must have nasal colonisation with the bacteria.

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**mupirocin 2% ointment, 3 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9440W NP | ‡1 | 0 | 0.00 | 24.05 | 25.00 | Bactroban [GK] |

**mupirocin 2% ointment, 5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11822F NP | ‡1 | 0 | 0.00 | 27.47 | 25.00 | Mupirocin Nasal (Medsurge) [DZ] |

# DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

## ADRENERGICS, INHALANTS

### *Selective beta-2-adrenoreceptor agonists*

### FORMOTEROL

**Restricted benefit**

***6355***

Asthma

**Clinical criteria:**

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; **OR**
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

**formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8239P NP | ‡1 | 5 | 0.00 | 25.00 | 25.00 | Oxis Turbuhaler [AP] |

**formoterol fumarate dihydrate 12 microgram powder for inhalation, 60 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8136F NP | 1 | 5 | 0.00 | 30.84 | 25.00 | Foradile [SZ] |

**formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8240Q NP | ‡1 | 5 | 0.00 | 30.36 | 25.00 | Oxis Turbuhaler [AP] |

## FORMOTEROL

**Restricted benefit**

***15607***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; **OR**
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

**formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14547P NP | ‡2 | 5 | 0.00 | *35.64 | 25.00 | Oxis Turbuhaler [AP] |

**formoterol fumarate dihydrate 12 microgram powder for inhalation, 60 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14419X NP | 2 | 5 | 0.00 | *47.32 | 25.00 | Foradile [SZ] |

**formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14517C NP | ‡2 | 5 | 0.00 | *46.36 | 25.00 | Oxis Turbuhaler [AP] |

## INDACATEROL

**Restricted benefit**

***6366***

Chronic obstructive pulmonary disease (COPD)

**Note** This drug is not PBS-subsidised for the treatment of asthma.

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA/LABA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** An ICS/LABA includes budesonide/formoterol, fluticasone/salmeterol, or fluticasone/vilanterol

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**indacaterol 150 microgram powder for inhalation, 30 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5134F NP | 1 | 5 | 0.00 | 58.90 | 25.00 | Onbrez [NV] |

**indacaterol 300 microgram powder for inhalation, 30 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5137J NP | 1 | 5 | 0.00 | 58.90 | 25.00 | Onbrez [NV] |

## INDACATEROL

**Restricted benefit**

***15736***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Note** This drug is not PBS-subsidised for the treatment of asthma.

**Note** The treatment must not be used in combination with an ICS/LABA, or LAMA/LABA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** An ICS/LABA includes budesonide/formoterol, fluticasone/salmeterol, or fluticasone/vilanterol

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**indacaterol 150 microgram powder for inhalation, 30 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14334K NP | 2 | 5 | 0.00 | *103.44 | 25.00 | Onbrez [NV] |

**indacaterol 300 microgram powder for inhalation, 30 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14368F NP | 2 | 5 | 0.00 | *103.44 | 25.00 | Onbrez [NV] |

## SALBUTAMOL

### salbutamol 100 microgram/actuation inhalation, 200 actuations

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 12109H | | | | | | | |
| NP | 2 | 5 | 0.00 | *25.68 | 25.00 | [a] Zempreon CFC-Free with dose counter [AL] | |
| | | | [B]0.88 | *26.56 | 25.00 | [a] Asmol CFC-Free with dose counter [AF] | |
| | | | [B]5.80 | *31.48 | 25.00 | [a] Ventolin CFC-Free with dose counter [GK] | |

## SALBUTAMOL

**Restricted benefit**

***6367***

Bronchospasm

**Clinical criteria:**

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

### salbutamol 100 microgram/actuation breath activated inhalation, 200 actuations

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8354Q | | | | | | |
| NP | 2 | 5 | 0.00 | *41.50 | 25.00 | Airomir Autohaler [IL] |

## SALBUTAMOL

**Note** Pharmaceutical benefits that have the brand Salbutamol (as sulfate) (Accord, UK) may be substituted for pharmaceutical benefits that have the brand Ventolin Nebules or Salbutamol Cipla in case of shortage.

**Restricted benefit**

***6815***

Asthma

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Note** Pharmaceutical benefits that have a 30 x 2 pack size and a 20 x 3 pack size are equivalent for the purposes of substitution.

**Restricted benefit**

***6825***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Note** Pharmaceutical benefits that have a 30 x 2 pack size and a 20 x 3 pack size are equivalent for the purposes of substitution.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

### salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2001H | | | | | | |
| NP | 2 | 5 | 0.00 | *24.82 | 25.00 | [a] Salbutamol Cipla [LR] |

### salbutamol 5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11095Y | | | | | | |
| NP | 3 | 5 | 0.00 | *32.55 | 25.00 | [a] Ventolin Nebules [GK] |

### salbutamol 5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15348T | | | | | | |
| NP | 3 | 5 | 0.00 | *173.04 | 25.00 | [a] Salbutamol (as sulfate) (Accord, UK) [OJ] |

## SALBUTAMOL

**Note** Pharmaceutical benefits that have the brand PMS-SALBUTAMOL (Canada) may be substituted for pharmaceutical benefits that have the brand Ventolin Nebules in the case of a shortage

**Restricted benefit**

***6815***

Asthma

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Restricted benefit**

***6825***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules**

| 11130T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *32.25 | 25.00 | [a] Ventolin Nebules [GK] |

**salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules**

| 13821K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *151.65 | 25.00 | [a] PMS-SALBUTAMOL (Canada) [RQ] |

## SALMETEROL

**Restricted benefit**

***6355***

Asthma

**Clinical criteria:**

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; **OR**
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

**salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| 8141L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 30.84 | 25.00 | Serevent Accuhaler [GK] |

## SALMETEROL

**Restricted benefit**

***15607***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; **OR**
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

**salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| 14328D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *47.32 | 25.00 | Serevent Accuhaler [GK] |

## TERBUTALINE

**Authority Required (STREAMLINED)**

***9828***

Bronchospasm

**Clinical criteria:**

- Patient must be unable to achieve co-ordinated use of a metered dose inhaler containing a short-acting beta-2 agonist; **OR**
- Patient must have developed a clinically important product-related adverse event during treatment with another short-acting beta-2 agonist.

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

**terbutaline sulfate 500 microgram/actuation powder for inhalation, 120 actuations**

| 12267P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *28.58 | 25.00 | Bricanyl Turbuhaler [AP] |

### *Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics*

## BECLOMETASONE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Note** This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

**Authority Required (STREAMLINED)**

***15469***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Population criteria:**

- Patient must be at least 18 years of age.

**beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

12183F

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 37.65 | 25.00 | [a] Cipla Beclometasone/Formoterol 100/6 [LR] | [a] Fostair [EU] |

## BECLOMETASONE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Note** This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

**Authority Required (STREAMLINED)**

***15599***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Population criteria:**

- Patient must be at least 18 years of age.

**beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

14376P

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *60.94 | 25.00 | [a] Cipla Beclometasone/Formoterol 100/6 [LR] | [a] Fostair [EU] |

## BECLOMETASONE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Note** This product is not PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

**Authority Required (STREAMLINED)**

***11057***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 18 years or older.

**beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

| 13205B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 47.53 | 25.00 | [a] Cipla Beclometasone/Formoterol 200/6 [LR] | [a] Fostair 200/6 [EU] |

## BECLOMETASONE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Note** This product is not PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

**Authority Required (STREAMLINED)**

***15656***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 18 years or older.

**beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

| 14538E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *80.70 | 25.00 | [a] Cipla Beclometasone/Formoterol 200/6 [LR] | [a] Fostair 200/6 [EU] |

## BUDESONIDE + FORMOTEROL

**Authority Required (STREAMLINED)**

***4380***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

| 8796Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 41.05 | 25.00 | Symbicort Turbuhaler 100/6 [AP] |

## BUDESONIDE + FORMOTEROL

**Authority Required (STREAMLINED)**

***4397***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; **OR**

- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

| 10015D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *42.32 | 25.00 | [a] Rilast RAPIHALER 100/3 [XT] | |
| | | | [B]4.82 | *47.14 | 25.00 | [a] Symbicort Rapihaler 100/3 [AP] | |

## BUDESONIDE + FORMOTEROL

**Authority Required (STREAMLINED)**

***10482***

Mild asthma

**Clinical criteria:**

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

**Population criteria:**

- Patient must be aged 12 years or over.

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

| 12042T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 2 | 0.00 | *42.32 | 25.00 | [a] Rilast RAPIHALER 100/3 [XT] | |
| | | | [B]4.82 | *47.14 | 25.00 | [a] Symbicort Rapihaler 100/3 [AP] | |

## BUDESONIDE + FORMOTEROL

**Authority Required (STREAMLINED)**

***15755***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

| 14440B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *67.74 | 25.00 | Symbicort Turbuhaler 100/6 [AP] |

## BUDESONIDE + FORMOTEROL

**Authority Required (STREAMLINED)**

***15702***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

| 14467K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *70.28 | 25.00 | [a] Rilast RAPIHALER 100/3 [XT] | |
| | | | [B]9.64 | *79.92 | 25.00 | [a] Symbicort Rapihaler 100/3 [AP] | |

## BUDESONIDE + FORMOTEROL

**Note** Patient must be aged 12 years or over.

**Authority Required (STREAMLINED)**

***7970***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

| 14151T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *37.66 | 25.00 | Bufomix Easyhaler 200/6 [OX] |

## BUDESONIDE + FORMOTEROL

**Note** Patient must be aged 12 years or over.

**Authority Required (STREAMLINED)**

***10464***

Mild asthma

**Clinical criteria:**

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

| 14166N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 2 | 0.00 | *37.66 | 25.00 | Bufomix Easyhaler 200/6 [OX] |

## BUDESONIDE + FORMOTEROL

**Note** Patient must be aged 12 years or over.

**Authority Required (STREAMLINED)**

***18055***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

| 15240D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *60.96 | 25.00 | Bufomix Easyhaler 200/6 [OX] |

## BUDESONIDE + FORMOTEROL

**Authority Required (STREAMLINED)**

***4404***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***10121***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.
**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

| 10018G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *60.38 | 25.00 | [a] Cipla Budesonide + Formoterol 200/6 [LR] | [a] Rilast RAPIHALER 200/6 [XT] |
| | | | [B]4.82 | *65.20 | 25.00 | [a] Symbicort Rapihaler 200/6 [AP] | |

## BUDESONIDE + FORMOTEROL

**Authority Required (STREAMLINED)**
***15615***
Asthma
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.
**Note** This product is not indicated for the initiation of treatment in asthma
**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**
***15548***
Chronic obstructive pulmonary disease (COPD)
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.
**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.
**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.
**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

| 14468L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *106.40 | 25.00 | [a] Cipla Budesonide + Formoterol 200/6 [LR] | [a] Rilast RAPIHALER 200/6 [XT] |
| | | | [B]9.72 | *116.12 | 25.00 | [a] Symbicort Rapihaler 200/6 [AP] | |

## BUDESONIDE + FORMOTEROL

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brands Bufomix EASYHALER 200/6, Symbicort Turbuhaler 200/6 and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.
**Note** Patient must be aged 12 years or over.

**Authority Required (STREAMLINED)**
***7970***
Asthma
**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; **OR**

- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

8625Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP ‡1 | 5 | 0.00 | 37.65 | 25.00 | [a] Bufomix EASYHALER 200/6 [OX] | [a] Rilast TURBUHALER 200/6 [XT] |
| | | [B]3.88 | 41.53 | 25.00 | [a] Symbicort Turbuhaler 200/6 [AP] | |

## BUDESONIDE + FORMOTEROL

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brands Bufomix EASYHALER 200/6, Symbicort Turbuhaler 200/6 and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 18 years or older.

**Authority Required (STREAMLINED)**

***7970***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

11273H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| NP ‡1 | 5 | 0.00 | 37.65 | 25.00 | [a] DuoResp Spiromax [EV] |

## BUDESONIDE + FORMOTEROL

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brands Bufomix EASYHALER 200/6, Symbicort Turbuhaler 200/6 and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 18 years or older.

**Authority Required (STREAMLINED)**

***10464***

Mild asthma

**Clinical criteria:**

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

12029D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| NP ‡1 | 2 | 0.00 | 37.65 | 25.00 | [a] DuoResp Spiromax [EV] |

## BUDESONIDE + FORMOTEROL

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brands Bufomix EASYHALER 200/6, Symbicort Turbuhaler 200/6 and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 12 years or over.

**Authority Required (STREAMLINED)**

***10464***

Mild asthma

**Clinical criteria:**

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

### budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

| 12041R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | 0.00 | 37.65 | 25.00 | [a] Bufomix EASYHALER 200/6 [OX] | [a] Rilast TURBUHALER 200/6 [XT] |
| | | | [B]3.88 | 41.53 | 25.00 | [a] Symbicort Turbuhaler 200/6 [AP] | |

## BUDESONIDE + FORMOTEROL

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brands Bufomix EASYHALER 200/6, Symbicort Turbuhaler 200/6 and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 18 years or older.

**Authority Required (STREAMLINED)**

***15680***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

### budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

| 14434Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *60.94 | 25.00 | [a] DuoResp Spiromax [EV] |

## BUDESONIDE + FORMOTEROL

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brands Bufomix EASYHALER 200/6, Symbicort Turbuhaler 200/6 and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 12 years or over.

**Authority Required (STREAMLINED)**

***15680***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; **OR**

- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; **OR**
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

14439Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP ‡2 | 5 | 0.00 | *60.94 | 25.00 | [a] Bufomix EASYHALER 200/6 [OX] | [a] Rilast TURBUHALER 200/6 [XT] |
| | | [B]7.76 | *68.70 | 25.00 | [a] Symbicort Turbuhaler 200/6 [AP] | |

## BUDESONIDE + FORMOTEROL

**Note** For prescriptions written for the Maximum Quantity of 2 inhalers (units), item code 11301T (2x60 pack) and item code 13258T (1x60 pack) are substitutable when dispensing 2 inhalers.

**Note** Pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations and pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations are equivalent for the purposes of substitution when dispensing 2 inhalers at one time.

**Authority Required (STREAMLINED)**

***7979***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Note** Patient must be aged 18 years or older.

**Note** Budesonide/formoterol fumarate dihydrate powder for inhalation 400/12 microgram strength inhalers are not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***10121***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations**

11301T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| NP ‡1 | 5 | 0.00 | 60.40 | 25.00 | [a] DuoResp Spiromax [EV] |

**budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

13258T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP 2 | 5 | 0.00 | *60.40 | 25.00 | [a] Bufomix Easyhaler 400/12 [OX] | [a] DuoResp Spiromax [EV] |
| | | | | | [a] Rilast TURBUHALER 400/12 [XT] | |
| | | [B]3.88 | 64.28 | 25.00 | [a] Symbicort TURBUHALER 400/12 [AP] | |

## BUDESONIDE + FORMOTEROL

**Note** For prescriptions written for the Maximum Quantity of 2 inhalers (units), item code 11301T (2x60 pack) and item code 13258T (1x60 pack) are substitutable when dispensing 2 inhalers.

**Note** Pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations and pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations are equivalent for the purposes of substitution when dispensing 2 inhalers at one time.

**Authority Required (STREAMLINED)**

***15617***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Note** Patient must be aged 18 years or older.

**Note** Budesonide/formoterol fumarate dihydrate powder for inhalation 400/12 microgram strength inhalers are not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***15548***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

### budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

| 14398T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *106.44 | 25.00 | [a] Bufomix Easyhaler 400/12 [OX] | [a] DuoResp Spiromax [EV] |
| | | | | | | [a] Rilast TURBUHALER 400/12 [XT] | |
| | | | [B]7.76 | 114.20 | 25.00 | [a] Symbicort TURBUHALER 400/12 [AP] | |

### budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations

| 14435R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *106.44 | 25.00 | [a] DuoResp Spiromax [EV] |

## BUDESONIDE + FORMOTEROL

**Note** Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***10538***

Asthma

**Clinical criteria:**

- Patient must have failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician; **OR**
- Must be treated by a paediatrician.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

12082X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡2 | 5 | 0.00 | *60.38 | 25.00 | [a] Cipla Budesonide + Formoterol 200/6 [LR] | [a] Rilast RAPIHALER 200/6 [XT] |
| | | [B]4.82 | *65.20 | 25.00 | [a] Symbicort Rapihaler 200/6 [AP] | |

## BUDESONIDE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***10538***

Asthma

**Clinical criteria:**

- Patient must have failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician; **OR**
- Must be treated by a paediatrician.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

12089G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡2 | 5 | 0.00 | *42.32 | 25.00 | [a] Rilast RAPIHALER 100/3 [XT] | |
| | | [B]4.82 | *47.14 | 25.00 | [a] Symbicort Rapihaler 100/3 [AP] | |

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

12101X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡1 | 5 | 0.00 | 41.05 | 25.00 | Symbicort Turbuhaler 100/6 [AP] |

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

12093L

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡1 | 5 | 0.00 | 37.65 | 25.00 | [a] Bufomix EASYHALER 200/6 [OX] | [a] DuoResp Spiromax [EV] |
| | | | | | [a] Rilast TURBUHALER 200/6 [XT] | |
| | | [B]3.88 | 41.53 | 25.00 | [a] Symbicort Turbuhaler 200/6 [AP] | |

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

14159F

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡2 | 5 | 0.00 | *37.66 | 25.00 | Bufomix Easyhaler 200/6 [OX] |

## BUDESONIDE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***15577***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician; **OR**
- Must be treated by a paediatrician.

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

14535B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡4 | 5 | 0.00 | *70.28 | 25.00 | [a] Rilast RAPIHALER 100/3 [XT] | |
| | | [B]9.64 | *79.92 | 25.00 | [a] Symbicort Rapihaler 100/3 [AP] | |

**budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

14437W

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| ‡2 | 5 | 0.00 | *67.74 | 25.00 | Symbicort Turbuhaler 100/6 [AP] |

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

14365C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡2 | 5 | 0.00 | *60.94 | 25.00 | [a] Bufomix EASYHALER 200/6 [OX] | [a] DuoResp Spiromax [EV] |
| | | | | | [a] Rilast TURBUHALER 200/6 [XT] | |
| | | [B]7.76 | 68.70 | 25.00 | [a] Symbicort Turbuhaler 200/6 [AP] | |

## BUDESONIDE + FORMOTEROL

**Note** Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***15577***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician; **OR**
- Must be treated by a paediatrician.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

14436T

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| ‡4 | 5 | 0.00 | *106.40 | 25.00 | [a] Cipla Budesonide + Formoterol 200/6 [LR] | [a] Rilast RAPIHALER 200/6 [XT] |
| | | [B]9.72 | *116.12 | 25.00 | [a] Symbicort Rapihaler 200/6 [AP] | |

## BUDESONIDE + FORMOTEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***18114***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition.

**Treatment criteria:**

- Must be treated by a respiratory physician; **OR**
- Must be treated by a paediatrician.

**budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15233R | 4 | 5 | 0.00 | *60.96 | 25.00 | Bufomix Easyhaler 200/6 [OX] |

## FLUTICASONE FUROATE + VILANTEROL

**Authority Required (STREAMLINED)**

***4731***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11129R NP | ‡1 | 5 | 0.00 | 70.15 | 25.00 | Breo Ellipta 200/25 [GK] |

## FLUTICASONE FUROATE + VILANTEROL

**Authority Required (STREAMLINED)**

***15692***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14345B NP | ‡2 | 5 | 0.00 | *126.52 | 25.00 | Breo Ellipta 200/25 [GK] |

## FLUTICASONE FUROATE + VILANTEROL

**Authority Required (STREAMLINED)**

***4711***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

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**Authority Required (STREAMLINED)**

***10121***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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### fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

| 11124L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 55.86 | 25.00 | Breo Ellipta 100/25 [GK] |

## FLUTICASONE FUROATE + VILANTEROL

**Authority Required (STREAMLINED)**

***15546***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

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**Authority Required (STREAMLINED)**

***15548***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| 14379T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *97.36 | 25.00 | Breo Ellipta 100/25 [GK] |

## FLUTICASONE PROPIONATE + FORMOTEROL

**Authority Required (STREAMLINED)**

***4395***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**fluticasone propionate 50 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

| 2827T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 39.40 | 25.00 | flutiform 50/5 [MF] |

**fluticasone propionate 125 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

| 10007Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 39.96 | 25.00 | flutiform 125/5 [MF] |

**fluticasone propionate 250 microgram/actuation + formoterol fumarate dihydrate 10 microgram/actuation inhalation, 120 actuations**

| 10008R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 51.32 | 25.00 | flutiform 250/10 [MF] |

## FLUTICASONE PROPIONATE + FORMOTEROL

**Authority Required (STREAMLINED)**

***15635***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

**Note** Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**fluticasone propionate 50 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

| 14411L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *64.44 | 25.00 | flutiform 50/5 [MF] |

**fluticasone propionate 125 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

| 14343X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *65.56 | 25.00 | flutiform 125/5 [MF] |

**fluticasone propionate 250 microgram/actuation + formoterol fumarate dihydrate 10 microgram/actuation inhalation, 120 actuations**

| 14344Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *88.28 | 25.00 | flutiform 250/10 [MF] |

## FLUTICASONE PROPIONATE + SALMETEROL

**Authority Required (STREAMLINED)**

***4930***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 4 years or older.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations**

| 8517G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 43.92 | 25.00 | [a] PAVTIDE MDI 50/25 [TX] | |
| | | | [B]3.88 | 47.80 | 25.00 | [a] Seretide MDI 50/25 [GK] | |

**fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| 8430Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 43.92 | 25.00 | [a] PAVTIDE ACCUHALER 100/50 [TX] | |
| | | | [B]3.88 | 47.80 | 25.00 | [a] Seretide Accuhaler 100/50 [GK] | |

**fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations**

| 8518H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 42.59 | 25.00 | [a] Evocair MDI [AF] | [a] Fluticasone + Salmeterol Cipla 125/25 [LR] |
| | | | | | | [a] Pavtide [TX] | [a] SalplusF Inhaler 125/25 [SZ] |
| | | | [B]4.85 | 47.44 | 25.00 | [a] Seretide MDI 125/25 [GK] | |

## FLUTICASONE PROPIONATE + SALMETEROL

**Authority Required (STREAMLINED)**

***15604***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 4 years or older.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations**

| 14414P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *73.48 | 25.00 | [a] PAVTIDE MDI 50/25 [TX] | |
| | | | [B]7.76 | *81.24 | 25.00 | [a] Seretide MDI 50/25 [GK] | |

**fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| 14413N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *73.48 | 25.00 | [a] PAVTIDE ACCUHALER 100/50 [TX] | |
| | | | [B]7.76 | *81.24 | 25.00 | [a] Seretide Accuhaler 100/50 [GK] | |

**fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations**

| 14544L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *70.82 | 25.00 | [a] Evocair MDI [AF] | [a] Fluticasone + Salmeterol Cipla 125/25 [LR] |
| | | | | | | [a] Pavtide [TX] | [a] SalplusF Inhaler 125/25 [SZ] |
| | | | [B]9.70 | 80.52 | 25.00 | [a] Seretide MDI 125/25 [GK] | |

## FLUTICASONE PROPIONATE + SALMETEROL

**Authority Required (STREAMLINED)**

***15118***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***10121***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| 8432T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 52.59 | 25.00 | [a] Fluticasone Salmeterol Ciphaler 500/50 [LR] | [a] PAVTIDE ACCUHALER 500/50 [TX] |
| | | | | | | [a] Salflumix Easyhaler 500/50 [OX] | [a] SalplusF DPI 500/50 [SZ] |
| | | | [B]3.88 | 56.47 | 25.00 | [a] Seretide Accuhaler 500/50 [GK] | |

## FLUTICASONE PROPIONATE + SALMETEROL

**Authority Required (STREAMLINED)**

***4930***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 4 years or older.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***10121***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations**

| 8519J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 52.59 | 25.00 | [a] Evocair MDI [AF] | [a] Fluticasone + Salmeterol Cipla 250/25 [LR] |
| | | | | | | [a] Pavtide [TX] | [a] SalplusF Inhaler 250/25 [SZ] |
| | | | [B]3.88 | 56.47 | 25.00 | [a] Seretide MDI 250/25 [GK] | |

## FLUTICASONE PROPIONATE + SALMETEROL

**Authority Required (STREAMLINED)**

***15715***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 4 years or older.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***15548***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations**

| 14311F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *90.82 | 25.00 | [a] Evocair MDI [AF] | [a] Fluticasone + Salmeterol Cipla 250/25 [LR] |
| | | | | | | [a] Pavtide [TX] | [a] SalplusF Inhaler 250/25 [SZ] |
| | | | [B]7.76 | 98.58 | 25.00 | [a] Seretide MDI 250/25 [GK] | |

## FLUTICASONE PROPIONATE + SALMETEROL

**Authority Required (STREAMLINED)**

***15714***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***15548***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| 14450M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *90.82 | 25.00 | [a] Fluticasone Salmeterol Ciphaler 500/50 [LR] | [a] PAVTIDE ACCUHALER 500/50 [TX] |
| | | | | | | [a] Salflumix Easyhaler 500/50 [OX] | [a] SalplusF DPI 500/50 [SZ] |
| | | | [B]7.76 | 98.58 | 25.00 | [a] Seretide Accuhaler 500/50 [GK] | |

## FLUTICASONE PROPIONATE + SALMETEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***15138***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| 8431R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 42.59 | 25.00 | [a] Fluticasone Salmeterol Ciphaler 250/50 [LR] | [a] PAVTIDE ACCUHALER 250/50 [TX] |
| | | | | | | [a] Salflumix Easyhaler 250/50 [OX] | [a] SalplusF DPI 250/50 [SZ] |
| | | | [B]4.85 | 47.44 | 25.00 | [a] Seretide Accuhaler 250/50 [GK] | |

## FLUTICASONE PROPIONATE + SALMETEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority Required (STREAMLINED)**

***15693***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations**

| 14449L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *70.82 | 25.00 | [a] Fluticasone Salmeterol Ciphaler 250/50 [LR] | [a] PAVTIDE ACCUHALER 250/50 [TX] |
| | | | | | | [a] Salflumix Easyhaler 250/50 [OX] | [a] SalplusF DPI 250/50 [SZ] |
| | | | [B]9.70 | 80.52 | 25.00 | [a] Seretide Accuhaler 250/50 [GK] | |

## INDACATEROL + MOMETASONE

**Authority Required (STREAMLINED)**

***11360***

Asthma

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This product is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**indacaterol 125 microgram + mometasone furoate 62.5 microgram powder for inhalation, 30 capsules**

| 12269R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 38.14 | 25.00 | Atectura Breezhaler [NV] |

**indacaterol 125 microgram + mometasone furoate 127.5 microgram powder for inhalation, 30 capsules**

| 12289T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 43.77 | 25.00 | Atectura Breezhaler [NV] |

**indacaterol 125 microgram + mometasone furoate 260 microgram powder for inhalation, 30 capsules**

| 12279G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 59.13 | 25.00 | Atectura Breezhaler [NV] |

## INDACATEROL + MOMETASONE

**Authority Required (STREAMLINED)**

***15653***

Asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

- Patient must be aged 12 years or over.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This product is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**indacaterol 125 microgram + mometasone furoate 62.5 microgram powder for inhalation, 30 capsules**

| 14332H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *61.92 | 25.00 | Atectura Breezhaler [NV] |

**indacaterol 125 microgram + mometasone furoate 127.5 microgram powder for inhalation, 30 capsules**

| 14333J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *73.18 | 25.00 | Atectura Breezhaler [NV] |

**indacaterol 125 microgram + mometasone furoate 260 microgram powder for inhalation, 30 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14441C NP | 2 | 5 | 0.00 | *103.90 | 25.00 | Atectura Breezhaler [NV] |

## *Adrenergics in combination with anticholinergics incl. triple combinations with corticosteroids*

### ACLIDINIUM + FORMOTEROL

**Authority Required (STREAMLINED)**

***7798***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); **OR**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); **OR**
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**aclidinium 340 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10565C NP | ‡1 | 5 | 0.00 | 78.59 | 25.00 | Brimica Genuair [FK] |

### ACLIDINIUM + FORMOTEROL

**Authority Required (STREAMLINED)**

***15691***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); **OR**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); **OR**
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**aclidinium 340 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14410K NP | ‡2 | 5 | 0.00 | *144.24 | 25.00 | Brimica Genuair [FK] |

### BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at http://copdx.org.au/); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**
***12349***
Chronic obstructive pulmonary disease (COPD)
**Clinical criteria:**

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; **OR**
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations**

| 12468F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 73.86 | 25.00 | Trimbow [EU] |

## BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at http://copdx.org.au/); the assessment and adherence to correct technique should be documented in the patient's medical records.
**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**
***15543***
Chronic obstructive pulmonary disease (COPD)
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; **OR**
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations**

| 14310E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *134.32 | 25.00 | Trimbow [EU] |

## BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).
**Note** This product is not indicated for the initiation of treatment in asthma
**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**
***12603***
Severe asthma
**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14606R NP | ‡1 | 5 | 0.00 | 73.86 | 25.00 | Trimbow [EU] |

## BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**

***18121***

Severe asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15243G NP | 2 | 5 | 0.00 | *134.32 | 25.00 | Trimbow [EU] |

## BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**

***12603***

Severe asthma

**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13200R NP | ‡1 | 5 | 0.00 | 78.84 | 25.00 | Trimbow [EU] |

## BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**

***18121***

Severe asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15232Q NP | 2 | 5 | 0.00 | *144.76 | 25.00 | Trimbow [EU] |

## BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at http://copdx.org.au/); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**

***12349***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; **OR**
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**budesonide 160 microgram/actuation + glycopyrronium 7.2 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12672Y NP | ‡1 | 5 | 0.00 | 77.91 | 25.00 | Breztri Aerosphere [AP] |

## BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at http://copdx.org.au/); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**

***15543***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; **OR**
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**budesonide 160 microgram/actuation + glycopyrronium 7.2 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations**

| 14536C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *142.82 | 25.00 | Breztri Aerosphere [AP] |

## FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at http://copdx.org.au/); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**

***12349***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; **OR**
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**fluticasone furoate 100 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| 11379X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 84.09 | 25.00 | Trelegy Ellipta 100/62.5/25 [GK] |

## FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at http://copdx.org.au/); the assessment and adherence to correct technique should be documented in the patient's medical records.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**
***15543***
Chronic obstructive pulmonary disease (COPD)
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; **OR**
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

**Treatment criteria:**

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

**fluticasone furoate 100 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| 14346C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *155.80 | 25.00 | Trelegy Ellipta 100/62.5/25 [GK] |

## FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).
**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).
**Note** This product is not indicated for the initiation of treatment in asthma
**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**
***12603***
Severe asthma
**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**fluticasone furoate 200 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| 12917W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 87.69 | 25.00 | Trelegy Ellipta 200/62.5/25 [GK] |

## FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).
**Note** This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).
**Note** This product is not indicated for the initiation of treatment in asthma
**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**
***15601***
Severe asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

### fluticasone furoate 200 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14382Y NP | ‡2 | 5 | 0.00 | *163.36 | 25.00 | Trelegy Ellipta 200/62.5/25 [GK] |

## INDACATEROL + GLYCOPYRRONIUM

**Authority Required (STREAMLINED)**

***7798***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); **OR**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); **OR**
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

### indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10156M NP | 1 | 5 | 0.00 | 85.69 | 25.00 | ultibro breezhaler 110/50 [NV] |

## INDACATEROL + GLYCOPYRRONIUM

**Authority Required (STREAMLINED)**

***15691***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); **OR**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); **OR**
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules**

| 14504J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *159.16 | 25.00 | ultibro breezhaler 110/50 [NV] |

## INDACATEROL + GLYCOPYRRONIUM + MOMETASONE

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**

***12603***

Severe asthma

**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 68 microgram powder for inhalation, 30 capsules**

| 12298G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 72.33 | 25.00 | Enerzair Breezhaler [NV] |

**indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 136 microgram powder for inhalation, 30 capsules**

| 12295D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 87.68 | 25.00 | Enerzair Breezhaler [NV] |

## INDACATEROL + GLYCOPYRRONIUM + MOMETASONE

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority Required (STREAMLINED)**

***15601***

Severe asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 68 microgram powder for inhalation, 30 capsules**

| 14471P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *131.10 | 25.00 | Enerzair Breezhaler [NV] |

**indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 136 microgram powder for inhalation, 30 capsules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14399W NP | 2 | 5 | 0.00 | *163.34 | 25.00 | Enerzair Breezhaler [NV] |

## TIOTROPIUM + OLODATEROL

**Authority Required (STREAMLINED)**

***7798***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); **OR**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); **OR**
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10557P NP | ‡1 | 5 | 0.00 | 74.09 | 25.00 | Spiolto Respimat [BY] |

## TIOTROPIUM + OLODATEROL

**Authority Required (STREAMLINED)**

***15691***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); **OR**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); **OR**
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**Note** This product is not PBS-subsidised for the treatment of asthma.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 2 x 60 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14849M NP | ‡1 | 5 | 0.00 | 134.80 | 25.00 | Spiolto Respimat [BY] |

## UMECLIDINIUM + VILANTEROL

**Authority Required (STREAMLINED)**

***7798***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); **OR**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); **OR**

- Patient must have been stabilised on a combination of a LAMA and a LABA.

**Note** This product is not PBS-subsidised for the treatment of asthma.
**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.
**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** A SAMA includes ipratropium
**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| 10188F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 85.68 | 25.00 | Anoro Ellipta 62.5/25 [GK] |

## UMECLIDINIUM + VILANTEROL

**Authority Required (STREAMLINED)**
***15691***
Chronic obstructive pulmonary disease (COPD)
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); **OR**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); **OR**
- Patient must have been stabilised on a combination of a LAMA and a LABA.

**Note** This product is not PBS-subsidised for the treatment of asthma.
**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.
**Note** The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA
**Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
**Note** A SAMA includes ipratropium
**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations**

| 14358Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *159.14 | 25.00 | Anoro Ellipta 62.5/25 [GK] |

# OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

## *Glucocorticoids*

## BECLOMETASONE

**beclometasone dipropionate 50 microgram/actuation inhalation, 200 actuations**

| 8406K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 21.22 | 22.76 | Qvar 50 [IL] |

**beclometasone dipropionate 100 microgram/actuation inhalation, 200 actuations**

| 8407L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 28.77 | 25.00 | Qvar 100 [IL] |

## BECLOMETASONE

**Restricted benefit**
***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**beclometasone dipropionate 50 microgram/actuation inhalation, 200 actuations**

| 14540G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *28.08 | 25.00 | Qvar 50 [IL] |

**beclometasone dipropionate 100 microgram/actuation inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14541H | | | | | | |
| NP | ‡2 | 5 | 0.00 | *43.18 | 25.00 | Qvar 100 [IL] |

## BUDESONIDE

**budesonide 100 microgram/actuation powder for inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2070Y | | | | | | |
| NP | ‡1 | 5 | 0.00 | 23.38 | 24.92 | Pulmicort Turbuhaler [AP] |

**budesonide 200 microgram/actuation powder for inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2071B | | | | | | |
| NP | ‡1 | 5 | 0.00 | 30.54 | 25.00 | Pulmicort Turbuhaler [AP] |

**budesonide 400 microgram/actuation powder for inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2072C | | | | | | |
| NP | ‡1 | 5 | 0.00 | 35.77 | 25.00 | Pulmicort Turbuhaler [AP] |

## BUDESONIDE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**budesonide 100 microgram/actuation powder for inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14331G | | | | | | |
| NP | ‡2 | 5 | 0.00 | *32.40 | 25.00 | Pulmicort Turbuhaler [AP] |

**budesonide 200 microgram/actuation powder for inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14503H | | | | | | |
| NP | ‡2 | 5 | 0.00 | *46.72 | 25.00 | Pulmicort Turbuhaler [AP] |

**budesonide 400 microgram/actuation powder for inhalation, 200 actuations**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14470N | | | | | | |
| NP | ‡2 | 5 | 0.00 | *57.18 | 25.00 | Pulmicort Turbuhaler [AP] |

## BUDESONIDE

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***6340***

Severe chronic asthma

**Clinical criteria:**

- Patient must require long-term steroid therapy, **AND**
- Patient must not be able to use other forms of inhaled steroid therapy.

**budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2065Q | | | | | | |
| NP | ‡1 | 5 | 0.00 | 87.37 | 25.00 | Pulmicort Respules [AP] |

**budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2066R | | | | | | |
| NP | ‡1 | 5 | 0.00 | 87.37 | 25.00 | Pulmicort Respules [AP] |

## BUDESONIDE

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***15578***

Severe chronic asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must require long-term steroid therapy, **AND**
- Patient must not be able to use other forms of inhaled steroid therapy.

**budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14438X | | | | | | |
| NP | ‡2 | 5 | 0.00 | *162.68 | 25.00 | Pulmicort Respules [AP] |

**budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules**

| 14469M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *162.68 | 25.00 | Pulmicort Respules [AP] |

## CICLESONIDE

**ciclesonide 80 microgram/actuation inhalation, 120 actuations**

| 8853Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 24.87 | 25.00 | Alvesco 80 [EU] |

**ciclesonide 160 microgram/actuation inhalation, 120 actuations**

| 8854B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 33.55 | 25.00 | Alvesco 160 [EU] |

## CICLESONIDE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**ciclesonide 80 microgram/actuation inhalation, 120 actuations**

| 14312G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *35.38 | 25.00 | Alvesco 80 [EU] |

**ciclesonide 160 microgram/actuation inhalation, 120 actuations**

| 14348E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *52.74 | 25.00 | Alvesco 160 [EU] |

## FLUTICASONE FUROATE

**fluticasone furoate 100 microgram/actuation powder for inhalation, 30 actuations**

| 11719T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 29.87 | 25.00 | Arnuity Ellipta [GK] |

**fluticasone furoate 200 microgram/actuation powder for inhalation, 30 actuations**

| 11729H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 42.90 | 25.00 | Arnuity Ellipta [GK] |

## FLUTICASONE FUROATE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**fluticasone furoate 100 microgram/actuation powder for inhalation, 30 actuations**

| 14515Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *45.38 | 25.00 | Arnuity Ellipta [GK] |

**fluticasone furoate 200 microgram/actuation powder for inhalation, 30 actuations**

| 14380W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *71.44 | 25.00 | Arnuity Ellipta [GK] |

## FLUTICASONE PROPIONATE

**fluticasone propionate 100 microgram/actuation powder for inhalation, 60 actuations**

| 8147T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 20.05 | 21.59 | [a] Axotide Junior Accuhaler [TX] | |
| | | | [B]3.87 | 23.92 | 21.59 | [a] Flixotide Junior Accuhaler [GK] | |

**fluticasone propionate 125 microgram/actuation inhalation, 120 actuations**

| 8345F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 27.28 | 25.00 | [a] Axotide [TX] | [a] Fluticasone Cipla Inhaler [LR] |
| | | | [B]2.91 | 30.19 | 25.00 | [a] Flixotide [GK] | |

**fluticasone propionate 250 microgram/actuation powder for inhalation, 60 actuations**

| 8148W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 27.28 | 25.00 | [a] Axotide Accuhaler [TX] | |
| | | | [B]3.88 | 31.16 | 25.00 | [a] Flixotide Accuhaler [GK] | |

**fluticasone propionate 250 microgram/actuation inhalation, 120 actuations**

| 8346G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 38.14 | 25.00 | [a] Axotide [TX] | [a] Fluticasone Cipla Inhaler [LR] |
| | | | [B]2.91 | 41.05 | 25.00 | [a] Flixotide [GK] | |

**fluticasone propionate 500 microgram/actuation powder for inhalation, 60 actuations**

| 8149X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 1 | 0.00 | 38.14 | 25.00 | Flixotide Accuhaler [GK] |

## FLUTICASONE PROPIONATE

**Authority Required (STREAMLINED)**

***14180***

Asthma

**Clinical criteria:**

- The treatment must not be a PBS benefit where this 50 microgram strength is being initiated in a patient over the age of 6.00 years.

**fluticasone propionate 50 microgram/actuation inhalation, 120 actuations**

| 8516F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 21.55 | 23.09 | [a] Axotide Junior [TX] | |
| | | | [B]3.88 | 25.43 | 23.09 | [a] Flixotide Junior [GK] | |

## FLUTICASONE PROPIONATE

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**fluticasone propionate 100 microgram/actuation powder for inhalation, 60 actuations**

| 14412M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *25.74 | 25.00 | [a] Axotide Junior Accuhaler [TX] | |
| | | | [B]7.74 | *33.48 | 25.00 | [a] Flixotide Junior Accuhaler [GK] | |

**fluticasone propionate 125 microgram/actuation inhalation, 120 actuations**

| 14347D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *40.20 | 25.00 | [a] Axotide [TX] | [a] Fluticasone Cipla Inhaler [LR] |
| | | | [B]5.82 | *46.02 | 25.00 | [a] Flixotide [GK] | |

**fluticasone propionate 250 microgram/actuation powder for inhalation, 60 actuations**

| 14381X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *40.20 | 25.00 | [a] Axotide Accuhaler [TX] | |
| | | | [B]7.76 | *47.96 | 25.00 | [a] Flixotide Accuhaler [GK] | |

## FLUTICASONE PROPIONATE

**Authority Required (STREAMLINED)**

***15854***

Asthma

**Clinical criteria:**

- The treatment must not be a PBS benefit where this 50 microgram strength is being initiated in a patient over the age of 6.00 years, **AND**
- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**fluticasone propionate 50 microgram/actuation inhalation, 120 actuations**

| 14487L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *28.74 | 25.00 | [a] Axotide Junior [TX] | |
| | | | [B]7.76 | *36.50 | 25.00 | [a] Flixotide Junior [GK] | |

### *Anticholinergics*

## ACLIDINIUM

**Restricted benefit**

***4516***

Chronic obstructive pulmonary disease (COPD)

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**aclidinium 322 microgram/actuation powder for inhalation, 60 actuations**

| 10124W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 58.90 | 25.00 | Bretaris Genuair [FK] |

## ACLIDINIUM

**Restricted benefit**

***15634***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**aclidinium 322 microgram/actuation powder for inhalation, 60 actuations**

| 14539F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *103.44 | 25.00 | Bretaris Genuair [FK] |

## GLYCOPYRRONIUM

**Restricted benefit**

***4516***

Chronic obstructive pulmonary disease (COPD)

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**glycopyrronium 50 microgram powder for inhalation, 30 capsules**

| 10059K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 58.90 | 25.00 | seebri breezhaler [NV] |

## GLYCOPYRRONIUM

**Restricted benefit**

***15634***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**glycopyrronium 50 microgram powder for inhalation, 30 capsules**

| 14417T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *103.44 | 25.00 | seebri breezhaler [NV] |

## IPRATROPIUM

**ipratropium bromide monohydrate 21 microgram/actuation inhalation, 200 actuations**

| 8671J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *34.86 | 25.00 | [a] Atrovent [BY] | [a] Cipla Ipratropium [LR] |

## IPRATROPIUM

**Restricted benefit**

***6331***

Asthma

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Restricted benefit**

***6341***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

### ipratropium bromide 250 microgram/mL inhalation solution, 30 x 1 mL ampoules

| 1542E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *27.74 | 25.00 | Atrovent [BY] |

### ipratropium bromide 500 microgram/mL inhalation solution, 30 x 1 mL ampoules

| 8238N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *30.18 | 25.00 | Atrovent Adult [BY] |

## TIOTROPIUM

**Restricted benefit**

***5509***

Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease

Treatment Phase: Long-term maintenance treatment

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

### tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

| 10509D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 44.42 | 25.00 | Spiriva Respimat [BY] |

## TIOTROPIUM

**Restricted benefit**

***12599***

Severe asthma

**Clinical criteria:**

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

### tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

| 11043F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 44.42 | 25.00 | Spiriva Respimat [BY] |

## TIOTROPIUM

**Authority Required (STREAMLINED)**

***8606***
Severe asthma
**Treatment criteria:**

- Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists.

**Clinical criteria:**

- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; **OR**
- Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

### tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

| 11629C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 44.42 | 25.00 | Spiriva Respimat [BY] |

## TIOTROPIUM

**Authority Required (STREAMLINED)**
***15754***
Severe asthma
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Treatment criteria:**

- Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists.

**Clinical criteria:**

- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; **OR**
- Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**tiotropium 2.5 microgram/actuation inhalation solution, 2 x 60 actuations**

| 14839B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 74.48 | 25.00 | Spiriva Respimat [BY] |

## TIOTROPIUM

**Restricted benefit**

***15753***

Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease

Treatment Phase: Long-term maintenance treatment

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**tiotropium 2.5 microgram/actuation inhalation solution, 2 x 60 actuations**

| 14842E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 74.48 | 25.00 | Spiriva Respimat [BY] |

## TIOTROPIUM

**Restricted benefit**

***15566***

Severe asthma

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**tiotropium 2.5 microgram/actuation inhalation solution, 2 x 60 actuations**

| 14845H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 74.48 | 25.00 | Spiriva Respimat [BY] |

## TIOTROPIUM

**Note** Pharmaceutical benefits that have the form tiotropium 18 microgram powder for inhalation and pharmaceutical benefits that have the form tiotropium 13 microgram powder for inhalation are equivalent for the purposes of substitution.

**Restricted benefit**

***6352***

Chronic obstructive pulmonary disease (COPD)

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**tiotropium 13 microgram powder for inhalation, 30 capsules**

| 11892X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 39.68 | 25.00 | [a] Braltus [TB] |

**tiotropium 18 microgram powder for inhalation, 30 capsules**

| 8626B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 44.42 | 25.00 | [a] Spiriva [BY] |

**tiotropium 18 microgram powder for inhalation, 30 capsules**

| 14576E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 39.68 | 25.00 | [a] Tiotropium Lupin [GQ] |

## TIOTROPIUM

**Note** Pharmaceutical benefits that have the form tiotropium 18 microgram powder for inhalation and pharmaceutical benefits that have the form tiotropium 13 microgram powder for inhalation are equivalent for the purposes of substitution.

**Restricted benefit**

***15611***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**tiotropium 13 microgram powder for inhalation, 30 capsules**

| 14555C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *65.00 | 25.00 | [a] Braltus [TB] |

**tiotropium 18 microgram powder for inhalation, 30 capsules**

| 14361W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *74.48 | 25.00 | [a] Spiriva [BY] |

**tiotropium 18 microgram powder for inhalation, 30 capsules**

| 14574C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *65.00 | 25.00 | [a] Tiotropium Lupin [GQ] |

## UMECLIDINIUM

**Restricted benefit**

***4516***

Chronic obstructive pulmonary disease (COPD)

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**umeclidinium 62.5 microgram powder for inhalation, 30 actuations**

| 10187E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 58.90 | 25.00 | Incruse Ellipta [GK] |

## UMECLIDINIUM

**Restricted benefit**

***15634***

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**umeclidinium 62.5 microgram powder for inhalation, 30 actuations**

| 14389H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡2 | 5 | 0.00 | *103.44 | 25.00 | Incruse Ellipta [GK] |

## ADRENERGICS FOR SYSTEMIC USE

### *Alpha- and beta-adrenoreceptor agonists*

### ADRENALINE (EPINEPHRINE)

**Note** Pharmaceutical benefits that have the form adrenaline 1 mg/mL ampoules for injection in a pack size of 10 can be substituted for a pack size of 5 in the case of a shortage.

**adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

| 1016L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 1 | 0.00 | 21.78 | 23.32 | Link Medical Products Pty Ltd [LM] |

**adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules**

| 5004J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 21.78 | 23.32 | Link Medical Products Pty Ltd [LM] |

### ADRENALINE (EPINEPHRINE)

**Caution** Adrenaline products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

**Note** The adrenaline devices should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No applications for repeats will be authorised.

**Authority Required**

***4909***

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority Required**

***8734***

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

**Authority Required**

***18922***

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

**adrenaline (epinephrine) 500 microgram/0.3 mL injection, 0.3 mL pen device**

| 12655C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *156.52 | 25.00 | Anapen 500 [XT] |

## ADRENALINE (EPINEPHRINE)

**Caution** Adrenaline products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

**Note** The adrenaline devices should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No applications for repeats will be authorised.

**Authority Required**

***18798***

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

**Population criteria:**

- Patient must be aged 4 years or older
- Patient must weigh 15 kg or more.

The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority Required**

***18795***

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

**Population criteria:**

- Patient must be aged 4 years or older
- Patient must weigh 15 kg or more.

**Authority Required**

***18924***

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

**Population criteria:**

- Patient must be aged 4 years or older
- Patient must weigh 15 kg or more.

### Adrenaline (epinephrine) 1 mg/actuation nasal spray, 2 x 1 actuation

| 15414G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 171.25 | 25.00 | neffy [CS] |

### Adrenaline (epinephrine) 2 mg/actuation nasal spray, 2 x 1 actuation

| 15404R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 171.25 | 25.00 | neffy [CS] |

## ADRENALINE (EPINEPHRINE)

**Caution** Adrenaline products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

**Note** The adrenaline devices should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au).

**Note** Pharmaceutical benefits that have the form adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device and pharmaceutical benefits that have the form adrenaline (epinephrine) 150 microgram/0.15 mL injection, 0.15 mL pen device are equivalent for the purposes of substitution.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No applications for repeats will be authorised.

**Authority Required**
***4909***
Acute allergic reaction with anaphylaxis
Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment
**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority Required**
***8734***
Acute allergic reaction with anaphylaxis
Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment
**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

**Authority Required**
***18922***
Acute allergic reaction with anaphylaxis
Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment
**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

### adrenaline (epinephrine) 150 microgram/0.15 mL injection, 0.15 mL pen device

15359J

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *156.52 | 25.00 | [a] Jext Jnr [KF] |

### adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device

8697R

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *156.52 | 25.00 | [a] Adrenaline Jr Viatris [AF] | [a] Anapen Junior 150 [XT] |
| | | | | | | [a] EpiPen Jr. [AL] | |

## ADRENALINE (EPINEPHRINE)

**Caution** Adrenaline products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.
**Note** The adrenaline devices should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au).
**Note** Pharmaceutical benefits that have the form adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device (Adrenaline Viatris, Anapen 300 and EpiPen) and pharmaceutical benefits that have the form adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device (Jext) are equivalent for the purposes of substitution.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No applications for repeats will be authorised.

**Authority Required**
***4909***
Acute allergic reaction with anaphylaxis
Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment
**Clinical criteria:**

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority Required**
***8734***
Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

**Authority Required**

***18922***

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

**adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device**

| 8698T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *156.52 | 25.00 | [a] Adrenaline Viatris [AF]<br>[a] EpiPen [AL] | [a] Anapen 300 [XT] |

**adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device**

| 15355E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 0 | 0.00 | *156.52 | 25.00 | [a] Jext [KF] |

### *Selective beta-2-adrenoreceptor agonists*

## SALBUTAMOL

**salbutamol 2 mg/5 mL oral liquid, 150 mL**

| 1103C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *27.66 | 25.00 | Ventolin [GK] |

## TERBUTALINE

**terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules**

| 1034K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 0 | 0.00 | 27.24 | 25.00 | Bricanyl [AP] |

## OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

### *Xanthines*

## THEOPHYLLINE

**Caution** Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

**theophylline 133.3 mg/25 mL oral liquid, 500 mL**

| 2614N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 19.05 | 20.59 | Nuelin [IL] |

**theophylline 200 mg modified release tablet, 100**

| 8230E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.75 | 20.29 | Nuelin-SR 200 [IL] |

**theophylline 250 mg modified release tablet, 100**

| 2634P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 19.58 | 21.12 | Nuelin-SR 250 [IL] |

**theophylline 300 mg modified release tablet, 100**

| 8231F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 20.62 | 22.16 | Nuelin-SR 300 [IL] |

### *Leukotriene receptor antagonists*

## MONTELUKAST

**Authority Required (STREAMLINED)**

***6666***

Asthma

Treatment Phase: First-line prevention

**Population criteria:**

- Patient must be aged 2 to 5 years inclusive.

**Clinical criteria:**

- The condition must be frequent intermittent; **OR**
- The condition must be mild persistent, **AND**

- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; **OR**
- The treatment must be an alternative to nedocromil sodium.

**Note** This drug is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

**Note** This drug is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**montelukast 4 mg chewable tablet, 28**

| 8627C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 18.69 | 20.23 | [a] APX-MONTELUKAST [TX] | [a] MONTELAIR 4 [RF] |
| | | | | | | [a] Montelukast Lupin [HQ] | [a] Montelukast Sandoz 4 [SZ] |
| | | | | | | [a] Montelukast Viatris [AL] | [a] MONTELUKAST-WGR [WG] |

## MONTELUKAST

**Authority Required (STREAMLINED)**

***15642***

Asthma

Treatment Phase: First-line prevention

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Population criteria:**

- Patient must be aged 2 to 5 years inclusive.

**Clinical criteria:**

- The condition must be frequent intermittent; **OR**
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; **OR**
- The treatment must be an alternative to nedocromil sodium.

**Note** This drug is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

**Note** This drug is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to this drug.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**montelukast 4 mg chewable tablet, 28**

| 14526M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *23.02 | 24.56 | [a] APX-MONTELUKAST [TX] | [a] MONTELAIR 4 [RF] |
| | | | | | | [a] Montelukast Lupin [HQ] | [a] Montelukast Sandoz 4 [SZ] |
| | | | | | | [a] Montelukast Viatris [AL] | [a] MONTELUKAST-WGR [WG] |

## MONTELUKAST

**Authority Required (STREAMLINED)**

***6674***

Asthma

Treatment Phase: First-line prevention

**Clinical criteria:**

- The condition must be frequent intermittent; **OR**
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; **OR**
- The treatment must be an alternative to nedocromil sodium.

**Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

**Note** This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***7781***

Asthma

Treatment Phase: Prevention of condition

**Clinical criteria:**

- The condition must be exercise-induced, **AND**
- The treatment must be as an alternative to adding salmeterol xinafoate; **OR**
- The treatment must be an alternative to adding formoterol fumarate, **AND**
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, **AND**
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

**Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

**Note** This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### montelukast 5 mg chewable tablet, 28

8628D

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 18.60 | 20.14 | [a] APX-MONTELUKAST [TX] | [a] MONTELAIR 5 [RF] |
| | | | | | [a] Montelukast Lupin [HQ] | [a] Montelukast Sandoz 5 [SZ] |
| | | | | | [a] Montelukast Viatris [AL] | [a] MONTELUKAST-WGR [WG] |

NP

## MONTELUKAST

**Authority Required (STREAMLINED)**

***15643***

Asthma

Treatment Phase: First-line prevention

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be frequent intermittent; **OR**
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; **OR**
- The treatment must be an alternative to nedocromil sodium.

**Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

**Note** This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***15644***

Asthma

Treatment Phase: Prevention of condition

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be exercise-induced, **AND**
- The treatment must be as an alternative to adding salmeterol xinafoate; **OR**
- The treatment must be an alternative to adding formoterol fumarate, **AND**
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, **AND**
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

**Population criteria:**

- Patient must be aged 6 to 14 years inclusive.

**Note** This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**montelukast 5 mg chewable tablet, 28**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14553Y NP | 2 | 5 | 0.00 | *22.84 | 24.38 | [a] APX-MONTELUKAST [TX] | [a] MONTELAIR 5 [RF] |
| | | | | | | [a] Montelukast Lupin [HQ] | [a] Montelukast Sandoz 5 [SZ] |
| | | | | | | [a] Montelukast Viatris [AL] | [a] MONTELUKAST-WGR [WG] |

# SENSORY ORGANS

## OPHTHALMOLOGICALS

### ANTIINFECTIVES

#### *Antibiotics*

### AZITHROMYCIN

**Note** Authority applications for increased quantities and/or repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 888 333.

**azithromycin 200 mg/5 mL powder for oral liquid, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8201P NP | ‡1 | 0 | 0.00 | 29.68 | 25.00 | Zithromax [PF] |

### AZITHROMYCIN

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**azithromycin 500 mg tablet, 2**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8336R NP MW | 4 | 0 | 0.00 | *31.24 | 25.00 | [a] APO-Azithromycin [TX] | [a] Azithromycin Sandoz [SZ] |
| | | | | | | [a] Azithromycin Viatris [AL] | [a] AZITHROMYCIN-WGR [WG] |
| | | | | | | [a] ZITHRO [RW] | [a] Zithromax [PF] |

### CHLORAMPHENICOL

**Restricted benefit**
***5835***
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**chloramphenicol 0.5% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11112W NP OP MW | ‡1 | 2 | 0.00 | 18.30 | 19.84 | Chlorsig [AS] |

#### *Antivirals*

### ACICLOVIR

**Restricted benefit**
***5965***
Herpes simplex keratitis

**aciclovir 3% eye ointment, 4.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1002R NP | ‡1 | 0 | 0.00 | 29.05 | 25.00 | [a] ViruPOS [AE] | [a] XOROX [IX] |

### ACICLOVIR

**Restricted benefit**
***5964***
Herpes simplex keratitis

**aciclovir 3% eye ointment, 4.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5501M OP | ‡1 | 0 | 0.00 | 29.05 | 25.00 | [a] ViruPOS [AE] | [a] XOROX [IX] |

#### *Fluoroquinolones*

### CIPROFLOXACIN

**Authority Required**

***4195***
Bacterial keratitis
**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ciprofloxacin 0.3% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1217C NP | 2 | 0 | 0.00 | *43.66 | 25.00 | [a] CiloQuin [NM] | |
| | | | [B]9.22 | *52.88 | 25.00 | [a] Ciloxan [NV] | |

## CIPROFLOXACIN

**Authority Required**
***4181***
Bacterial keratitis
**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ciprofloxacin 0.3% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5564W OP | 2 | 0 | 0.00 | *43.66 | 25.00 | [a] CiloQuin [NM] | |
| | | | [B]9.22 | *52.88 | 25.00 | [a] Ciloxan [NV] | |

## OFLOXACIN

**Authority Required**
***4181***
Bacterial keratitis
**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ofloxacin 0.3% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5567B OP | 2 | 0 | 0.00 | *29.76 | 25.00 | Ocuflox [VE] |

## OFLOXACIN

**Authority Required**
***4195***
Bacterial keratitis
**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**ofloxacin 0.3% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8383F NP | 2 | 0 | 0.00 | *29.76 | 25.00 | Ocuflox [VE] |

# ANTIINFLAMMATORY AGENTS

## *Corticosteroids, plain*

## DEXAMETHASONE

**Authority Required**
***7566***
Non-infectious posterior segment uveitis
**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 6/12 or worse in the eye proposed for treatment, secondary to vitreous haze or macular oedema, **AND**
- Patient must have unilateral, asymmetric or bilateral flare-up where systemic treatment or further intensification of systemic treatment is not clinically indicated.

**dexamethasone 700 microgram implant, 1**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11317P | 1 | 0 | 0.00 | 1,202.87 | 25.00 | Ozurdex [VE] |

## DEXAMETHASONE

**Note** Special Pricing Arrangements apply.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Authority Required (STREAMLINED)**

***13428***

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have had a cataract removed in the treated eye; **OR**
- Patient must be scheduled for cataract surgery in the treated eye, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**dexamethasone 700 microgram implant, 1**

13168C

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 1,202.87 | 25.00 | Ozurdex [VE] |

## DEXAMETHASONE

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17387***

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have had a cataract removed in the treated eye; **OR**
- Patient must be scheduled for cataract surgery in the treated eye, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; **OR**
- Patient must be unsuitable for treatment with VEGF inhibitors; **OR**
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

Details (date, unique identifying number/code or provider number) of one of the following diagnostic reports for each eye must be documented in the patient's medical records:

(i) fluorescein angiogram report;

(ii) optical coherence tomography report.

**dexamethasone 700 microgram implant, 1**

10943Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 1 | 0.00 | 1,202.87 | 25.00 | Ozurdex [VE] |

## DEXAMETHASONE

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Authority Required**

***18428***

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; **OR**
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***18336***

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; **OR**
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### dexamethasone 700 microgram implant, 1

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11469P | 1 | 1 | 0.00 | 1,202.87 | 25.00 | Ozurdex [VE] |

## DEXAMETHASONE

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Authority Required (STREAMLINED)**

***13387***

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required (STREAMLINED)**

***13336***

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### dexamethasone 700 microgram implant, 1

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13142Q | 1 | 1 | 0.00 | 1,202.87 | 25.00 | Ozurdex [VE] |

## HYDROCORTISONE ACETATE

### hydrocortisone acetate 1% eye ointment, 5 g

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2441L | ‡1 | 0 | 0.00 | 19.67 | 21.21 | Hycor [AS] |
| NP | | | | | | |

## HYDROCORTISONE ACETATE

**Note** No applications for increased maximum quantities will be authorised.
**Note** No applications for increased repeats will be authorised.

**hydrocortisone acetate 1% eye ointment, 5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5516H OP | ‡1 | 0 | 0.00 | 19.67 | 21.21 | Hycor [AS] |

### *Corticosteroids and mydriatics in combination*

## PREDNISOLONE ACETATE + PHENYLEPHRINE

**Restricted benefit**
***6087***
Uveitis

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5568C OP | ‡1 | 0 | 0.00 | 24.70 | 25.00 | Prednefrin Forte [VE] |

## PREDNISOLONE ACETATE + PHENYLEPHRINE

**Restricted benefit**
***10095***
Severe eye inflammation
**Clinical criteria:**

- Patient must have had a cataract removed in the treated eye; **OR**
- Patient must be scheduled for cataract surgery in the treated eye.

**Population criteria:**

- Patient must identify as Aboriginal or Torres Strait Islander.

**prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11908R | ‡1 | 0 | 0.00 | 24.70 | 25.00 | Prednefrin Forte [VE] |

## PREDNISOLONE ACETATE + PHENYLEPHRINE

**Restricted benefit**
***6080***
Corneal grafts
**Restricted benefit**
***6101***
Uveitis

**prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3112T NP | ‡1 | 2 | 0.00 | 24.70 | 25.00 | Prednefrin Forte [VE] |

# ANTIGLAUCOMA PREPARATIONS AND MIOTICS

### *Sympathomimetics in glaucoma therapy*

## BRIMONIDINE

**brimonidine tartrate 0.2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8351M NP | ‡1 | 5 | 0.00 | 22.29 | 23.83 | [a] Enidin [VB] | |
| | | | [B]0.95 | 23.24 | 23.83 | [a] Alphagan [VE] | |

## BRIMONIDINE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brimonidine tartrate 0.2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5534G OP | ‡1 | 5 | 0.00 | 22.29 | 23.83 | [a] Enidin [VB] | |
| | | | [B]0.95 | 23.24 | 23.83 | [a] Alphagan [VE] | |

## BRIMONIDINE

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**brimonidine tartrate 0.2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14497B NP OP | ‡2 | 5 | 0.00 | *30.22 | 25.00 | [a] Enidin [VB] | |
| | | | [B]1.90 | *32.12 | 25.00 | [a] Alphagan [VE] | |

## BRIMONIDINE + TIMOLOL

**Restricted benefit**
***5038***
Elevated intra-ocular pressure
**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5535H OP | ‡1 | 5 | 0.00 | 26.70 | 25.00 | Combigan [VE] |

## BRIMONIDINE + TIMOLOL

**Restricted benefit**
***4343***
Elevated intra-ocular pressure
**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8826M NP | ‡1 | 5 | 0.00 | 26.70 | 25.00 | Combigan [VE] |

## BRIMONIDINE + TIMOLOL

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**
***15558***
Elevated intra-ocular pressure
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14491Q NP OP | ‡2 | 5 | 0.00 | *39.04 | 25.00 | Combigan [VE] |

### *Parasympathomimetics*

## PILOCARPINE

**pilocarpine hydrochloride 1% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2595N NP | ‡1 | 5 | 0.00 | 19.54 | 21.08 | Isopto Carpine [NV] |

**pilocarpine hydrochloride 2% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2596P NP | ‡1 | 5 | 0.00 | 20.57 | 22.11 | Isopto Carpine [NV] |

**pilocarpine hydrochloride 4% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2598R NP | ‡1 | 5 | 0.00 | 22.98 | 24.52 | Isopto Carpine [NV] |

## PILOCARPINE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

### pilocarpine hydrochloride 1% eye drops, 15 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5536J OP | ‡1 | 5 | 0.00 | 19.54 | 21.08 | Isopto Carpine [NV] |

### pilocarpine hydrochloride 2% eye drops, 15 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5537K OP | ‡1 | 5 | 0.00 | 20.57 | 22.11 | Isopto Carpine [NV] |

### pilocarpine hydrochloride 4% eye drops, 15 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5538L OP | ‡1 | 5 | 0.00 | 22.98 | 24.52 | Isopto Carpine [NV] |

## PILOCARPINE

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

### pilocarpine hydrochloride 1% eye drops, 15 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14355M NP OP | ‡2 | 5 | 0.00 | *24.72 | 25.00 | Isopto Carpine [NV] |

### pilocarpine hydrochloride 2% eye drops, 15 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14523J NP OP | ‡2 | 5 | 0.00 | *26.78 | 25.00 | Isopto Carpine [NV] |

### pilocarpine hydrochloride 4% eye drops, 15 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14550T NP OP | ‡2 | 5 | 0.00 | *31.60 | 25.00 | Isopto Carpine [NV] |

## *Carbonic anhydrase inhibitors*

## ACETAZOLAMIDE

**Restricted benefit**

***16559***

For prescribing by certain health practitioners

**Treatment criteria:**

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner who is continuing treatment with this medicine (of any strength) that was initiated by a medical practitioner as a PBS benefit.

### acetazolamide 250 mg tablet, 100

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1004W NP | 1 | 3 | 0.00 | 28.50 | 25.00 | Diamox [RW] |

## BRINZOLAMIDE

### brinzolamide 1% eye drops, 5 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8483L NP | ‡1 | 5 | 0.00 | 23.81 | 25.00 | [a] BrinzoQuin [NM] | |
| | | | [B]6.59 | 30.40 | 25.00 | [a] Azopt [NV] | |

## BRINZOLAMIDE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

### brinzolamide 1% eye drops, 5 mL

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5540N OP | ‡1 | 5 | 0.00 | 23.81 | 25.00 | [a] BrinzoQuin [NM] | |
| | | | [B]6.59 | 30.40 | 25.00 | [a] Azopt [NV] | |

## BRINZOLAMIDE

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**brinzolamide 1% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14321R NP OP | ‡2 | 5 | 0.00 | *33.26 | 25.00 | [a] BrinzoQuin [NM] | |
| | | | [B]13.18 | *46.44 | 25.00 | [a] Azopt [NV] | |

## BRINZOLAMIDE + BRIMONIDINE

**Restricted benefit**

***4343***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10536M NP | ‡1 | 5 | 0.00 | 25.36 | 25.00 | Simbrinza 1%/0.2% [NV] |

## BRINZOLAMIDE + BRIMONIDINE

**Restricted benefit**

***5038***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10547D OP | ‡1 | 5 | 0.00 | 25.36 | 25.00 | Simbrinza 1%/0.2% [NV] |

## BRINZOLAMIDE + BRIMONIDINE

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

***15558***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14423D NP OP | ‡2 | 5 | 0.00 | *36.36 | 25.00 | Simbrinza 1%/0.2% [NV] |

## BRINZOLAMIDE + TIMOLOL

**Restricted benefit**

***4343***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3438Y NP | ‡1 | 5 | 0.00 | 23.83 | 25.00 | Azarga [NV] |

## BRINZOLAMIDE + TIMOLOL

**Restricted benefit**

***5038***
Elevated intra-ocular pressure
**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5562R OP | ‡1 | 5 | 0.00 | 23.83 | 25.00 | Azarga [NV] |

## BRINZOLAMIDE + TIMOLOL

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**
***15558***
Elevated intra-ocular pressure
**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14495X NP OP | ‡2 | 5 | 0.00 | *33.30 | 25.00 | Azarga [NV] |

## DORZOLAMIDE

**dorzolamide 2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8488R NP | ‡1 | 5 | 0.00 | 19.53 | 21.07 | [a] Trusamide [AF] | [a] Trusopt [MF] |

## DORZOLAMIDE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**dorzolamide 2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5541P OP | ‡1 | 5 | 0.00 | 19.53 | 21.07 | [a] Trusamide [AF] | [a] Trusopt [MF] |

## DORZOLAMIDE

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**
***14238***
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**dorzolamide 2% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14524K NP OP | ‡2 | 5 | 0.00 | *24.70 | 25.00 | [a] Trusamide [AF] | [a] Trusopt [MF] |

## DORZOLAMIDE + TIMOLOL

**Restricted benefit**
***5038***
Elevated intra-ocular pressure
**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5542Q OP | ‡1 | 5 | 0.00 | 22.94 | 24.48 | [a] Cosdor [AF] | [a] Vizo-PF Dorzolatim [AE] |
| | | | [B]0.47 | 23.41 | 24.48 | [a] Cosopt [MF] | |

## DORZOLAMIDE + TIMOLOL

**Restricted benefit**

***4343***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8567X NP | ‡1 | 5 | 0.00 | 22.94 | 24.48 | [a] Cosdor [AF] | [a] Vizo-PF Dorzolatim [AE] |
| | | | [B]0.47 | 23.41 | 24.48 | [a] Cosopt [MF] | |

## DORZOLAMIDE + TIMOLOL

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

***15558***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**dorzolamide 2% + timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14386E NP OP | ‡2 | 5 | 0.00 | *31.52 | 25.00 | [a] Cosdor [AF] | [a] Vizo-PF Dorzolatim [AE] |
| | | | [B]0.94 | *32.46 | 25.00 | [a] Cosopt [MF] | |

### *Beta blocking agents*

## TIMOLOL

**timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1926J NP | ‡1 | 5 | 0.00 | 24.16 | 25.00 | Timoptol XE [MF] |

**timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 1279H NP | ‡1 | 5 | 0.00 | 22.38 | 23.92 | [a] TIMOEYE [DZ] | [a] Timoptol [MF] |

## TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5550D OP | ‡1 | 5 | 0.00 | 24.16 | 25.00 | Timoptol XE [MF] |

**timolol 0.5% eye drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5548B OP | ‡1 | 5 | 0.00 | 22.38 | 23.92 | [a] TIMOEYE [DZ] | [a] Timoptol [MF] |

## TIMOLOL

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15062R NP OP | 2 | 5 | 0.00 | *33.96 | 25.00 | Timoptol XE [MF] |

**timolol 0.5% eye drops, 5 mL**

| 15048B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP OP | 2 | 5 | 0.00 | *30.40 | 25.00 | [a] TIMOEYE [DZ] | [a] Timoptol [MF] |

***Prostaglandin analogues***

## BIMATOPROST

**bimatoprost 0.03% eye drops, 30 x 0.4 mL ampoules**

| 10046R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 30.43 | 25.00 | Lumigan PF [VE] |

**bimatoprost 0.03% eye drops, 3 mL**

| 8620Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 33.50 | 25.00 | [a] Bimatoprost Sandoz [SZ] | [a] BIMATOPROST-WGR [WG] |
| | | | | | | [a] Bimprozt [TY] | [a] Lumigan [VE] |

## BIMATOPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**bimatoprost 0.03% eye drops, 30 x 0.4 mL ampoules**

| 10053D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | 0.00 | 30.43 | 25.00 | Lumigan PF [VE] |

**bimatoprost 0.03% eye drops, 3 mL**

| 5551E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | 0.00 | 33.50 | 25.00 | [a] Bimatoprost Sandoz [SZ] | [a] BIMATOPROST-WGR [WG] |
| | | | | | | [a] Bimprozt [TY] | [a] Lumigan [VE] |

## BIMATOPROST

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**bimatoprost 0.03% eye drops, 30 x 0.4 mL ampoules**

| 14422C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP OP | ‡2 | 5 | 0.00 | *46.50 | 25.00 | Lumigan PF [VE] |

**bimatoprost 0.03% eye drops, 3 mL**

| 14315K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP OP | ‡2 | 5 | 0.00 | *52.64 | 25.00 | [a] Bimatoprost Sandoz [SZ] | [a] BIMATOPROST-WGR [WG] |
| | | | | | | [a] Bimprozt [TY] | [a] Lumigan [VE] |

## BIMATOPROST + TIMOLOL

**Restricted benefit**

***5038***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL ampoules**

| 10108B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | 0.00 | 35.04 | 25.00 | GANfort PF 0.3/5 [VE] |

**bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL**

| 5558M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | 0.00 | 37.24 | 25.00 | Ganfort 0.3/5 [VE] |

## BIMATOPROST + TIMOLOL

**Restricted benefit**

***4343***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10107Y NP | ‡1 | 5 | 0.00 | 35.04 | 25.00 | GANfort PF 0.3/5 [VE] |

**bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9464D NP | ‡1 | 5 | 0.00 | 37.24 | 25.00 | Ganfort 0.3/5 [VE] |

## BIMATOPROST + TIMOLOL

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

***15558***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL ampoules**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14351H NP OP | ‡2 | 5 | 0.00 | *55.72 | 25.00 | GANfort PF 0.3/5 [VE] |

**bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14317M NP OP | ‡2 | 5 | 0.00 | *60.12 | 25.00 | Ganfort 0.3/5 [VE] |

## LATANOPROST

**latanoprost 0.005% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8243W NP | ‡1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Latanoprost [TX] | [a] Latanoprost Sandoz [SZ] |
| | | | | | | [a] Xalaprost [AF] | [a] Xalatan [AS] |

## LATANOPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**latanoprost 0.005% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5552F OP | ‡1 | 5 | 0.00 | 18.60 | 20.14 | [a] APO-Latanoprost [TX] | [a] Latanoprost Sandoz [SZ] |
| | | | | | | [a] Xalaprost [AF] | [a] Xalatan [AS] |

## LATANOPROST

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**latanoprost 0.005% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14453Q NP OP | ‡2 | 5 | 0.00 | *22.84 | 24.38 | [a] APO-Latanoprost [TX] | [a] Latanoprost Sandoz [SZ] |
| | | | | | | [a] Xalaprost [AF] | [a] Xalatan [AS] |

## LATANOPROST + TIMOLOL

**Restricted benefit**

***5038***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**

- Patient must have ocular hypertension.

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 5553G OP | ‡1 | 5 | 0.00 | 22.27 | 23.81 | [a] APO-Latanoprost/Timolol 0.05/5 [TX]<br>[a] Xalamol 50/5 [AF] | [a] Xalacom [AS] |

## LATANOPROST + TIMOLOL

**Restricted benefit**

***4343***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 8895E NP | ‡1 | 5 | 0.00 | 22.27 | 23.81 | [a] APO-Latanoprost/Timolol 0.05/5 [TX]<br>[a] Xalamol 50/5 [AF] | [a] Xalacom [AS] |

## LATANOPROST + TIMOLOL

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

***15558***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14350G NP OP | ‡2 | 5 | 0.00 | *30.18 | 25.00 | [a] APO-Latanoprost/Timolol 0.05/5 [TX]<br>[a] Xalamol 50/5 [AF] | [a] Xalacom [AS] |

## TRAVOPROST

**travoprost 0.004% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8597L NP | ‡1 | 5 | 0.00 | 33.50 | 25.00 | Travatan [NV] |

## TRAVOPROST

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**travoprost 0.004% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5554H OP | ‡1 | 5 | 0.00 | 33.50 | 25.00 | Travatan [NV] |

## TRAVOPROST

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**travoprost 0.004% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14549R NP OP | ‡2 | 5 | 0.00 | *52.64 | 25.00 | Travatan [NV] |

## TRAVOPROST + TIMOLOL

**Restricted benefit**

***5038***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5555J OP | ‡1 | 5 | 0.00 | 36.36 | 25.00 | Duotrav [NV] |

## TRAVOPROST + TIMOLOL

**Restricted benefit**

***4343***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9057Q NP | ‡1 | 5 | 0.00 | 36.36 | 25.00 | Duotrav [NV] |

## TRAVOPROST + TIMOLOL

**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**

***15558***

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14316L NP OP | ‡2 | 5 | 0.00 | *58.36 | 25.00 | Duotrav [NV] |

# MYDRIATICS AND CYCLOPLEGICS

## *Anticholinergics*

## ATROPINE SULFATE

**atropine sulfate monohydrate 1% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1093M NP | ‡1 | 2 | 0.00 | 31.57 | 25.00 | Atropt [AS] |

# OCULAR VASCULAR DISORDER AGENTS

## *Antineovascularisation agents*

## AFLIBERCEPT

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- aflibercept 0.09 mL injection syringe, and
- aflibercept 0.165 mL injection syringe, and
- aflibercept 0.1 mL injection vial.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***13392***

Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to pathologic myopia (PM), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| 13139M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 304.55 | 25.00 | [a] Eylea [BN] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| 15218Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 304.55 | 25.00 | [a] Afqlir [ZE] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

| 13151E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 306.54 | 25.00 | [a] Eylea [BN] |

## AFLIBERCEPT

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- aflibercept 0.09 mL injection syringe, and
- aflibercept 0.165 mL injection syringe, and
- aflibercept 0.1 mL injection vial.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***13406***

Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

| 13146X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 306.54 | 25.00 | [a] Eylea [BN] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| 13167B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 304.55 | 25.00 | [a] Eylea [BN] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| 15219B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 304.55 | 25.00 | [a] Afqlir [ZE] |

## AFLIBERCEPT

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- aflibercept 0.09 mL injection syringe, and
- aflibercept 0.165 mL injection syringe, and
- aflibercept 0.1 mL injection vial.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***13402***

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| 13150D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 304.55 | 25.00 | [a] Eylea [BN] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| 15215T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 304.55 | 25.00 | [a] Afqlir [ZE] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

| 13164W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 306.54 | 25.00 | [a] Eylea [BN] |

## AFLIBERCEPT

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Pharmaceutical benefits that have the form aflibercept 8 mg/0.07 mL injection syringe and pharmaceutical benefits that have the form aflibercept 8 mg/0.07 mL injection vial are equivalent for the purposes of substitution.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***13406***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**aflibercept 8 mg/0.07 mL injection, 0.07 mL vial**

| 14594D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 443.80 | 25.00 | [a] Eylea [BN] |

**aflibercept 8 mg/0.07 mL injection, 0.07 mL syringe**

| 15221D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 428.34 | 25.00 | [a] Eylea [BN] |

## AFLIBERCEPT

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form aflibercept 8 mg/0.07 mL injection syringe and pharmaceutical benefits that have the form aflibercept 8 mg/0.07 mL injection vial are equivalent for the purposes of substitution.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15918***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

### aflibercept 8 mg/0.07 mL injection, 0.07 mL vial

| 14626T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 443.80 | 25.00 | [a] Eylea [BN] |

### aflibercept 8 mg/0.07 mL injection, 0.07 mL syringe

| 15260E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 428.34 | 25.00 | [a] Eylea [BN] |

## AFLIBERCEPT

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Pharmaceutical benefits that have the form aflibercept 8 mg/0.07 mL injection syringe and pharmaceutical benefits that have the form aflibercept 8 mg/0.07 mL injection vial are equivalent for the purposes of substitution.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***13402***

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**aflibercept 8 mg/0.07 mL injection, 0.07 mL vial**

| 14627W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 443.80 | 25.00 | [a] Eylea [BN] |

**aflibercept 8 mg/0.07 mL injection, 0.07 mL syringe**

| 15220C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 428.34 | 25.00 | [a] Eylea [BN] |

## AFLIBERCEPT

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Pharmaceutical benefits that have the form aflibercept 8 mg/0.07 mL injection syringe and pharmaceutical benefits that have the form aflibercept 8 mg/0.07 mL injection vial are equivalent for the purposes of substitution.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17289***

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

Details (date, unique identifying number/code or provider number) of one of the following diagnostic reports for each eye must be documented in the patient's medical records:

(i) fluorescein angiogram report;

(ii) optical coherence tomography report.

**aflibercept 8 mg/0.07 mL injection, 0.07 mL vial**

| 14635G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 443.80 | 25.00 | [a] Eylea [BN] |

**aflibercept 8 mg/0.07 mL injection, 0.07 mL syringe**

| 15248M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 428.34 | 25.00 | [a] Eylea [BN] |

## AFLIBERCEPT

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- aflibercept 0.09 mL injection syringe, and
- aflibercept 0.165 mL injection syringe, and
- aflibercept 0.1 mL injection vial.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required (STREAMLINED)**

***13387***

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required (STREAMLINED)**

***13336***

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

| 13138L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 306.54 | 25.00 | [a] Eylea [BN] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| 13141P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 304.55 | 25.00 | [a] Eylea [BN] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| 15206H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 304.55 | 25.00 | [a] Afqlir [ZE] |

## AFLIBERCEPT

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- aflibercept 0.09 mL injection syringe, and
- aflibercept 0.165 mL injection syringe, and
- aflibercept 0.1 mL injection vial.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***18146***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to pathologic myopia (PM), **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

| 12131L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 306.54 | 25.00 | [a] Eylea [BN] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| 12141B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 304.55 | 25.00 | [a] Eylea [BN] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| 15213Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 304.55 | 25.00 | [a] Afqlir [ZE] |

## AFLIBERCEPT

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- aflibercept 0.09 mL injection syringe, and
- aflibercept 0.165 mL injection syringe, and
- aflibercept 0.1 mL injection vial.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***15918***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2168D | 1 | 2 | 0.00 | 306.54 | 25.00 | [a] Eylea [BN] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12152N | 1 | 2 | 0.00 | 304.55 | 25.00 | [a] Eylea [BN] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15217X | 1 | 2 | 0.00 | 304.55 | 25.00 | [a] Afqlir [ZE] |

## AFLIBERCEPT

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- aflibercept 0.09 mL injection syringe, and
- aflibercept 0.165 mL injection syringe, and
- aflibercept 0.1 mL injection vial.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17289***

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

Details (date, unique identifying number/code or provider number) of one of the following diagnostic reports for each eye must be documented in the patient's medical records:

(i) fluorescein angiogram report;

(ii) optical coherence tomography report.

**aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10505X | 1 | 5 | 0.00 | 306.54 | 25.00 | [a] Eylea [BN] |

## AFLIBERCEPT

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- aflibercept 0.09 mL injection syringe, and
- aflibercept 0.165 mL injection syringe, and
- aflibercept 0.1 mL injection vial.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***17289***

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

Details (date, unique identifying number/code or provider number) of one of the following diagnostic reports for each eye must be documented in the patient's medical records:

(i) fluorescein angiogram report;

(ii) optical coherence tomography report.

### aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe

| 12153P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 304.55 | 25.00 | [a] Eylea [BN] |

### aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe

| 15214R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 304.55 | 25.00 | [a] Afqlir [ZE] |

## AFLIBERCEPT

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

**Note** Pharmaceutical benefits that have the following forms are equivalent for the purposes of substitution:

- aflibercept 0.09 mL injection syringe, and
- aflibercept 0.165 mL injection syringe, and
- aflibercept 0.1 mL injection vial.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***18144***

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18145***

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**aflibercept 2 mg/0.05 mL injection, 0.05 mL vial**

| 11991D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 306.54 | 25.00 | [a] Eylea [BN] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| 12132M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 304.55 | 25.00 | [a] Eylea [BN] |

**aflibercept 2 mg/0.05 mL injection, 0.05 mL syringe**

| 15207J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 304.55 | 25.00 | [a] Afqlir [ZE] |

## BROLUCIZUMAB

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18490***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- Patient must have persistent macular exudation, as determined clinically and/or by optical coherence tomography or fluorescein angiography, despite at least 6 months of PBS-subsidised treatment with: 1. Aflibercept and/or 2. Ranibizumab and/or 3. Faricimab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority Required**

***13426***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### brolucizumab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12667Q | 1 | 2 | 0.00 | 979.42 | 25.00 | Beovu [NV] |

## FARICIMAB

**Note** Pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL injection vial and pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL injection syringe are equivalent for the purposes of substitution.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16482***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13183W | 1 | 2 | 0.00 | 915.49 | 25.00 | [a] Vabysmo [RO] |

**faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe**

| 14788H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 915.49 | 25.00 | [a] Vabysmo [RO] |

## FARICIMAB

**Note** Pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL injection vial and pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL injection syringe are equivalent for the purposes of substitution.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***13406***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial**

| 13195L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 915.49 | 25.00 | [a] Vabysmo [RO] |

**faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe**

| 14799X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 915.49 | 25.00 | [a] Vabysmo [RO] |

## FARICIMAB

**Note** Pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL injection vial and pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL injection syringe are equivalent for the purposes of substitution.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***13402***

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial**

| 13198P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 915.49 | 25.00 | [a] Vabysmo [RO] |

**faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe**

| 14817W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 915.49 | 25.00 | [a] Vabysmo [RO] |

## FARICIMAB

**Note** Pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL injection vial and pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL injection syringe are equivalent for the purposes of substitution.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17289***

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

Details (date, unique identifying number/code or provider number) of one of the following diagnostic reports for each eye must be documented in the patient's medical records:

(i) fluorescein angiogram report;

(ii) optical coherence tomography report.

### faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial

13177M

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 915.49 | 25.00 | [a] Vabysmo [RO] |

### faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe

14789J

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 915.49 | 25.00 | [a] Vabysmo [RO] |

## FARICIMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL injection vial and pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL injection syringe are equivalent for the purposes of substitution.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***16319***

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Authority Required**

***16309***

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

### faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial

| 14737P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 915.49 | 25.00 | [a] Vabysmo [RO] |

### faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe

| 14873T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 915.49 | 25.00 | [a] Vabysmo [RO] |

## FARICIMAB

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL injection vial and pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL injection syringe are equivalent for the purposes of substitution.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***13387***

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Authority Required (STREAMLINED)**

***13336***

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

### faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial

| 14738Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 915.49 | 25.00 | [a] Vabysmo [RO] |

### faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe

| 14864H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 915.49 | 25.00 | [a] Vabysmo [RO] |

## RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority Required (STREAMLINED)**

***13406***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

| 13157L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

### ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

| 13137K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

## RANIBIZUMAB

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***15918***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

### ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

| 10138N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

### ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

| 1382R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

## RANIBIZUMAB

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***17288***

Proliferative diabetic retinopathy (PDR) and/or Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment. This is only a requirement for patients being treated for DMO, **AND**
- The condition must be diagnosed by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography; **OR**

- The condition must be diagnosed by retinal photography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this indication for the same eye.

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

Details (date, unique identifying number/code or provider number) of one of the following diagnostic reports for each eye must be documented in the patient's medical records:

(i) fluorescein angiogram report;

(ii) optical coherence tomography report;

(iii) retinal photography report.

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

10374B

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

10373Y

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

## RANIBIZUMAB

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Applications for increased maximum quantities to treat both eyes may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***17395***

Proliferative diabetic retinopathy (PDR) and/or Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation.

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

13134G

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

13165X

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 1 | 5 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

## RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority Required**

***18146***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to pathologic myopia (PM), **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority Required**

***18147***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must not be due to pathologic myopia, **AND**
- The condition must not be due to age-related macular degeneration, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

| 11480F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

| 11471R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

## RANIBIZUMAB

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***18144***

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority Required**

***18145***

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**

- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

1) details of the proposed prescription; and
2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

All reports must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe

| 11975G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

### ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

| 11981N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

## RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority Required (STREAMLINED)**

***13392***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must be due to pathologic myopia (PM), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required (STREAMLINED)**

***13340***

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- The condition must not be due to pathologic myopia, **AND**
- The condition must not be due to age-related macular degeneration, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

| 13143R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

| 13156K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

## RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority Required (STREAMLINED)**

***13387***

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority Required (STREAMLINED)**

***13336***

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

| 13166Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

| 13149C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 2 | 0.00 | 763.96 | 25.00 | [a] Lucentis [NV] |

# OTHER OPHTHALMOLOGICALS

## *Other ophthalmologicals*

## CARBOMER-980

**Restricted benefit**

***15560***

Severe dry eye syndrome

**carbomer-980 0.2% eye gel, 10 g**

| 5503P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | 0.00 | 17.72 | 19.26 | [a] Optifresh eye gel [PP] | [a] PAA [UL] |
| | | | [B]3.63 | 21.35 | 19.26 | [a] Viscotears [UO] | |

**carbomer-980 0.2% eye gel, 10 g**

| 8384G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 17.72 | 19.26 | [a] Optifresh eye gel [PP] | [a] PAA [UL] |
| | | | [B]3.63 | 21.35 | 19.26 | [a] Viscotears [UO] | |

## CARBOMER-980

**Authority Required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carbomer-980 0.2% eye drops, 30 x 600 mg ampoules**

| 5504Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | 3 | 5 | 0.00 | *31.53 | 25.00 | Viscotears Gel PF [UO] |

**carbomer-980 0.2% eye drops, 30 x 600 mg ampoules**

| 8578L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *31.53 | 25.00 | Viscotears Gel PF [UO] |

## CARBOMER-980

**Restricted benefit**

***15556***

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**carbomer-980 0.2% eye gel, 10 g**

| 14385D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP OP | ‡2 | 5 | 0.00 | *21.08 | 22.62 | [a] Optifresh eye gel [PP] | [a] PAA [UL] |
| | | | [B]7.26 | *28.34 | 22.62 | [a] Viscotears [UO] | |

## CARBOMER-980

**Authority Required (STREAMLINED)**

***15559***

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**carbomer-980 0.2% eye drops, 30 x 600 mg ampoules**

| 14420Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP OP | 6 | 5 | 0.00 | *48.66 | 25.00 | Viscotears Gel PF [UO] |

## CARMELLOSE SODIUM

**Note** The in-use shelf life of this product is 3 months from the date of opening.

**Authority Required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**carmellose sodium 0.5% eye drops, 10 mL**

| 11852T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 25.56 | 25.00 | Evolve Carmellose [CX] |

**carmellose sodium 0.5% eye drops, 10 mL**

| 11853W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | 0.00 | 25.56 | 25.00 | Evolve Carmellose [CX] |

## CARMELLOSE SODIUM

**Note** The in-use shelf life of this product is 3 months from the date of opening.

**Authority Required (STREAMLINED)**

***15559***

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

### carmellose sodium 0.5% eye drops, 10 mL

| 14319P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP OP | ‡2 | 5 | 0.00 | *36.76 | 25.00 | Evolve Carmellose [CX] |

## CICLOSPORIN

**Caution** It is recommended that the potential for immunosuppression with long term use of this drug be clinically reviewed after at least 24 months of treatment, if not already reviewed.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority Required**

***14026***

Chronic severe dry eye disease with keratitis

Treatment Phase: Initial treatment for up to the first 180 days of treatment

**Clinical criteria:**

- Patient must have a corneal fluorescein staining (CFS) grade of 4 at treatment initiation, using at least one of: (i) the Oxford scale, (ii) the modified Oxford scale, (iii) an equivalent scale to the Oxford scale as determined by the prescriber, **AND**
- Patient must have an ocular surface disease index (OSDI) score of at least 23 at treatment initiation, **AND**
- The condition must be inadequately controlled by monotherapy with a preservative free artificial tears substitute, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Patient must be undergoing simultaneous treatment with a preservative free artificial tears substitute, **AND**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; **OR**
- Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines, **AND**
- Patient must not be undergoing treatment with this drug under this treatment phase beyond day 180 of treatment.

**Population criteria:**

- Patient must be at least 18 years of age.

Prescribing instruction:

State in the first authority application for this drug, for the purpose of having a baseline measurement to assess response to treatment under the Continuing treatment listing, each of: (i) the qualifying corneal fluorescein staining grade (a numerical value no less than 4), (ii) the qualifying ocular surface disease index score (a numerical value no less than 23).

**Note** The Oxford scale, modified Oxford scale and Ocular Surface Disease Index (OSDI) were relied upon in the submission supporting initial PBS listing.

The Oxford scale uses a chart system consisting of a series of panels, labelled A to E in order of increasing severity. In each chart, staining is represented by dots. To grade staining, comparisons are made between the panels and the appearance of staining on the exposed interpalpebral conjunctiva and cornea of the patient. The details of the chart are presented in Figure 1 and, in a simplified form in Figure 4 (where the criteria, dot count and log columns are not displayed), in the following literature article: Bron A, Evans V, Smith, J. Grading of corneal and conjunctival staining in the context of other dry eye tests. Cornea. 2003;22(7):640-650.

The modified Oxford scale is as above, but with the first grade depiction (Grade 0), termed 'Grade 0.5'.

A list of equivalent scales to the Oxford scale is not provided. Prescribers should be satisfied that a scale other than the Oxford scale, if used, is equivalent to the Oxford scale.

The Ocular Surface Disease Index (OSDI) is a 12-item questionnaire created by the Outcomes Research Group at Allergan Inc, Irvine, CA, USA, to assess dry eye symptoms and the effects on vision-related function.

The questionnaire has 3 subscales: ocular symptoms, vision-related function, and environmental triggers. Patients rate their responses on a 0 to 4 scale with 0 corresponding to 'none of the time' and 4 corresponding to 'all of the time'. A final score is calculated which ranges from 0 to 100 with scores 0 to 12 representing normal, 13 to 22 representing mild dry eye disease, 23 to 32 representing moderate dry eye disease, and greater than 33 representing severe dry eye disease.

The OSDI questionnaire asks the following:

Presence of ocular symptoms - Have you experienced any of the following during the last week?

1. Eyes that are sensitive to light 2. Eyes that feel gritty 3. Painful or sore eyes 4. Blurred vision 5. Poor vision

Impact on daily activities - Have you had problems with your eyes limited you in performing any of the following during the last week?

1. Reading 2. Driving at night 3. Working with a computer or bank machine (ATM) 4. Watching TV

Environmental factors - Have your eyes felt uncomfortable in any of the following situations during the last week?

1. Windy conditions 2. Places or areas with low humidity (very dry) 3. Areas that are airconditioned

Rate responses on a scale of 0 to 4; 0 = none of the time, 1 = some of the time, 2 = half of the time, 3 = most of the time, and 4 = all of the time.

Further information on this index is in the following literature article: Walt J, Rowe M, Stern K. Evaluating the functional impact of dry eye: the Ocular Surface Disease Index. Drug Information Journal. 1997;31:1436

The 'Dry Eye OSDI 'Questionnaire' app developed by Allergan Inc is available to download for iPhone.

**Note** If the maximum number of repeats stated in this listing is not requested in this application, further supplies can be obtained through this treatment phase listing to continue treatment for up to the first 180 days of treatment, but the OSDI score and CFS grade need not be re-stated. Alternatively, treatment may be continued under the 'Continuing treatment' phase listing, provided the patient meets all eligibility criteria specified in that treatment phase listing.

**Authority Required**

***14032***

Chronic severe dry eye disease with keratitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must have improved to an extent that corneal fluorescein staining, using the same scale used at the time of the first authority application, shows an improvement (reduction) by at least 3 grades from baseline (the grade stated in the first authority application) - the improvement need only be demonstrated by staining once only with the first Continuing treatment authority application, **AND**
- The condition must have improved to an extent that the patient's ocular surface disease index score at the time of this authority application, has improved (reduced) by at least 30% compared to the value stated in the first authority application (i.e. baseline), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; **OR**
- Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines.

Prescribing instructions:

State in the first continuing treatment authority application for this drug:

(i) an improved corneal fluorescein staining grade (a numerical value that has improved by 3 grades from that provided in the first Initial 1 treatment authority application).

State in all continuing treatment authority applications:

(ii) the ocular surface disease index score at the time of this authority application (a numerical value that is at least 30% lower than that stated in the first Initial 1 treatment authority application).

### ciclosporin 0.09% eye drops, 60 x 0.25 mL ampoules

| 13284E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | 1 | 5 | 0.00 | 82.16 | 25.00 | Cequa [RA] |

### ciclosporin 0.1% eye drops, 30 x 0.3 mL ampoules

| 12663L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | 0.00 | 82.16 | 25.00 | Ikervis [CS] |

### Ciclosporin 0.1% eye drops, 2 mL

| 15541Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | 0.00 | 77.64 | 25.00 | Vevye [AE] |

## DEXTRAN-70 + HYPROMELLOSE

**Restricted benefit**

***15560***

Severe dry eye syndrome

### dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

| 1509K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 18.10 | 19.64 | [a] Poly-Tears [IQ] | |
| | | | [B]3.79 | 21.89 | 19.64 | [a] Tears Naturale [AQ] | |

### dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

| 5520M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | 0.00 | 18.10 | 19.64 | [a] Poly-Tears [IQ] | |
| | | | [B]3.79 | 21.89 | 19.64 | [a] Tears Naturale [AQ] | |

## DEXTRAN-70 + HYPROMELLOSE

**Restricted benefit**

***15556***

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 14521G NP OP | ‡2 | 5 | 0.00 | *21.84 | 23.38 | [a] Poly-Tears [IQ] | |
| | | | [B]7.58 | *29.42 | 23.38 | [a] Tears Naturale [AQ] | |

## HYALURONATE SODIUM

**Note** The in-use shelf life of this product is 6 months from the date of opening

**Authority Required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**hyaluronate sodium 0.2% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2171G OP | ‡1 | 5 | 0.00 | 35.07 | 25.00 | Hylo-Forte [AE] |

**hyaluronate sodium 0.2% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2253N NP | ‡1 | 5 | 0.00 | 35.07 | 25.00 | Hylo-Forte [AE] |

**hyaluronate sodium 0.1% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2181T NP | ‡1 | 5 | 0.00 | 35.07 | 25.00 | Hylo-Fresh [AE] |

**hyaluronate sodium 0.1% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2184Y OP | ‡1 | 5 | 0.00 | 35.07 | 25.00 | Hylo-Fresh [AE] |

## HYALURONATE SODIUM

**Note** The in-use shelf life of this product is 6 months from the date of opening

**Authority Required (STREAMLINED)**

***15559***

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**hyaluronate sodium 0.1% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14354L NP OP | ‡2 | 5 | 0.00 | *55.78 | 25.00 | Hylo-Fresh [AE] |

**hyaluronate sodium 0.2% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14494W NP OP | ‡2 | 5 | 0.00 | *55.78 | 25.00 | Hylo-Forte [AE] |

## HYPROMELLOSE

**Restricted benefit**

***15560***

Severe dry eye syndrome

**hypromellose 0.3% w/w eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11625W NP | ‡1 | 5 | 0.00 | 17.10 | 18.64 | Revive Tears [PP] |

**hypromellose 0.3% w/w eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11634H OP | ‡1 | 5 | 0.00 | 17.10 | 18.64 | Revive Tears [PP] |

**hypromellose 0.5% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2956N NP | ‡1 | 5 | 0.00 | 18.10 | 19.64 | Methopt [AF] |

**hypromellose 0.5% eye drops, 15 mL**

| 5517J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | 0.00 | 18.10 | 19.64 | Methopt [AF] |

## HYPROMELLOSE

**Restricted benefit**

***15556***

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**hypromellose 0.3% w/w eye drops, 10 mL**

| 14318N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP OP | ‡2 | 5 | 0.00 | *19.84 | 21.38 | Revive Tears [PP] |

**hypromellose 0.5% eye drops, 15 mL**

| 14320Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP OP | ‡2 | 5 | 0.00 | *21.84 | 23.38 | Methopt [AF] |

## HYPROMELLOSE

**Note** The in-use shelf life of this product is 3 months from the date of opening.

**Authority Required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**hypromellose 0.3% w/v eye drops, 10 mL**

| 11842G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | ‡1 | 5 | 0.00 | 25.56 | 25.00 | Evolve Hypromellose [CX] |

**hypromellose 0.3% w/v eye drops, 10 mL**

| 11849P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 5 | 0.00 | 25.56 | 25.00 | Evolve Hypromellose [CX] |

## HYPROMELLOSE

**Note** The in-use shelf life of this product is 3 months from the date of opening.

**Authority Required (STREAMLINED)**

***15559***

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**hypromellose 0.3% w/v eye drops, 10 mL**

| 14492R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP OP | ‡2 | 5 | 0.00 | *36.76 | 25.00 | Evolve Hypromellose [CX] |

## LIQUID PARAFFIN + GLYCEROL + TYLOXAPOL + POLOXAMER-188 + TROMETAMOL HYDROCHLORIDE + TROMETAMOL + CETALKONIUM CHLORIDE

**Note** The in-use shelf life of this product is 3 months from the date of opening.

**Authority Required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**liquid paraffin + glycerol + tyloxapol + poloxamer-188 + trometamol hydrochloride + trometamol + cetalkonium chloride eye drops, 10 mL**

| 12612T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP OP | ‡1 | 5 | 0.00 | 36.03 | 25.00 | Cationorm [CS] |

## LIQUID PARAFFIN + GLYCEROL + TYLOXAPOL + POLOXAMER-188 + TROMETAMOL HYDROCHLORIDE + TROMETAMOL + CETALKONIUM CHLORIDE

**Note** The in-use shelf life of this product is 3 months from the date of opening.

**Authority Required (STREAMLINED)**

***15559***

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**liquid paraffin + glycerol + tyloxapol + poloxamer-188 + trometamol hydrochloride + trometamol + cetalkonium chloride eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14352J NP OP | ‡2 | 5 | 0.00 | *57.70 | 25.00 | Cationorm [CS] |

## PARAFFIN

**paraffin 1 g/g eye ointment, 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1754H NP | 2 | 5 | 0.00 | *22.00 | 23.54 | Poly Visc [IQ] |

**paraffin 1 g/g eye ointment, 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5523Q OP | 2 | 5 | 0.00 | *22.00 | 23.54 | Poly Visc [IQ] |

## PARAFFIN

**Restricted benefit**

***14238***

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**paraffin 1 g/g eye ointment, 3.5 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14353K NP OP | 4 | 5 | 0.00 | *29.64 | 25.00 | Poly Visc [IQ] |

## PERFLUOROHEXYLOCTANE

**Authority Required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**Note** The in-use shelf life of Novatears is 6 months from the date of opening.

**perfluorohexyloctane 100% eye drops, 3 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11439C OP | 1 | 5 | 0.00 | 34.18 | 25.00 | Novatears [AE] |

**perfluorohexyloctane 100% eye drops, 3 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11446K NP | 1 | 5 | 0.00 | 34.18 | 25.00 | Novatears [AE] |

## PERFLUOROHEXYLOCTANE

**Note** The in-use shelf life of Novatears is 6 months from the date of opening.

**Authority Required (STREAMLINED)**

***15559***

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**perfluorohexyloctane 100% eye drops, 3 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14424E NP OP | 2 | 5 | 0.00 | *54.00 | 25.00 | Novatears [AE] |

## POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Restricted benefit**

***15560***

Severe dry eye syndrome

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5524R OP | ‡1 | 5 | 0.00 | 16.91 | 18.45 | Systane [AQ] |

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8676P NP | ‡1 | 5 | 0.00 | 16.91 | 18.45 | Systane [AQ] |

## POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Authority Required (STREAMLINED)**

***6172***

Severe dry eye syndrome

**Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15272T NP | 2 | 5 | 0.00 | *33.32 | 25.00 | Systane [AQ] |

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15326P OP | 2 | 5 | 0.00 | *33.32 | 25.00 | Systane [AQ] |

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13100L NP | 2 | 5 | 0.00 | *34.68 | 25.00 | Systane [AQ] |

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13113E OP | 2 | 5 | 0.00 | *34.68 | 25.00 | Systane [AQ] |

## POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Restricted benefit**

***15556***

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14421B NP OP | ‡2 | 5 | 0.00 | *19.46 | 21.00 | Systane [AQ] |

## POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

**Authority Required (STREAMLINED)**

***15559***

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15320H NP OP | 4 | 5 | 0.00 | *52.28 | 25.00 | Systane [AQ] |

**polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14520F NP OP | 4 | 5 | 0.00 | *55.00 | 25.00 | Systane [AQ] |

## PROPYLENE GLYCOL

**Note** The in-use shelf life of this product is 6 months from the date of opening

**Restricted benefit**

***16387***

Severe dry eye syndrome

**propylene glycol 0.6% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14768G NP OP | ‡1 | 5 | 0.00 | 17.16 | 18.70 | Systane Balance [AQ] |

## PROPYLENE GLYCOL

**Note** The in-use shelf life of this product is 6 months from the date of opening

**Restricted benefit**

***15556***

Severe dry eye syndrome

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**propylene glycol 0.6% eye drops, 10 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15242F NP OP | 2 | 5 | 0.00 | *19.96 | 21.50 | Systane Balance [AQ] |

# OTOLOGICALS

## ANTIINFECTIVES

### *Antiinfectives*

## CIPROFLOXACIN

**Authority Required**

***5593***

Chronic suppurative otitis media

**Population criteria:**

- Patient must be an Aboriginal or a Torres Strait Islander person
- Patient must be aged 1 month or older.

**Authority Required**

***5551***

Chronic suppurative otitis media

**Population criteria:**

- Patient must be less than 18 years of age.

**Clinical criteria:**

- Patient must have perforation of the tympanic membrane.

**Authority Required**

***5535***

Chronic suppurative otitis media

**Population criteria:**

- Patient must be less than 18 years of age.

**Clinical criteria:**

- Patient must have a grommet in situ.

**ciprofloxacin 0.3% ear drops, 5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2480M NP | ‡1 | 1 | 0.00 | 40.00 | 25.00 | Ciloxan [NV] |

## CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION

### *Corticosteroids and antiinfectives in combination*

## FRAMYCETIN SULFATE + GRAMICIDIN + DEXAMETHASONE

**framycetin sulfate 0.5% + gramicidin 0.005% + dexamethasone 0.05% ear drops, 8 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2781J NP | ‡1 | 2 | 0.00 | 17.95 | 19.49 | [a] Otodex [FQ] | |
| | | | [B]2.24 | 20.19 | 19.49 | [a] Sofradex [PB] | |

## TRIAMCINOLONE + NEOMYCIN + GRAMICIDIN + NYSTATIN

**triamcinolone acetonide 0.09% + neomycin 0.225% + gramicidin 0.0225% + nystatin 90 000 units/mL ear drops, 7.5 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| 2971J NP | ‡1 | 2 | 0.00 | 18.38 | 19.92 | [a] Otocomb Otic [LN] | |
| | | | [B]1.58 | 19.96 | 19.92 | [a] Kenacomb Otic [AS] | |

**triamcinolone acetonide 0.1% + neomycin 0.25% + gramicidin 0.025% + nystatin 100 000 units/g ointment, 5 g**

| 2974M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | ‡1 | 2 | 0.00 | 17.10 | 18.64 | [a] Otocomb Otic [LN] | |
| | | | [B]2.66 | 19.76 | 18.64 | [a] Kenacomb Otic [AS] | |

# OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

## ANTIINFECTIVES

### *Antiinfectives*

### FRAMYCETIN SULFATE

**framycetin sulfate 0.5% eye/ear drops, 8 mL**

| 1440T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | ‡1 | 2 | 0.00 | 17.45 | 18.99 | Soframycin [PB] |

**framycetin sulfate 0.5% eye/ear drops, 8 mL**

| 5557L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| OP | ‡1 | 2 | 0.00 | 17.45 | 18.99 | Soframycin [PB] |

# VARIOUS

## ALLERGENS

### ALLERGENS

### *Allergen extracts*

### HONEY BEE VENOM

**honey bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack**

| 2886X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 354.34 | 25.00 | Albey Bee Venom [DE] |

### PAPER WASP VENOM

**Note** Paper wasp venom is not European wasp venom

**paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack**

| 10620Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 338.88 | 25.00 | Hymenoptera Paper Wasp Venom [DE] |

**paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack**

| 2918N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 354.34 | 25.00 | Albey Paper Wasp Venom [DE] |

### YELLOW JACKET VENOM

**yellow jacket venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack**

| 2883R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 354.34 | 25.00 | Albey Yellow Jacket Venom [DE] |

# ALL OTHER THERAPEUTIC PRODUCTS

## ALL OTHER THERAPEUTIC PRODUCTS

### *Antidotes*

### NALOXONE

**naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules**

| 10783M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 31.28 | 25.00 | [a] Naloxone Hydrochloride (DBL) [PF] | [a] Naloxone Juno [JU] |
| | | | | | | [a] NALOXONE SXP [XN] | |

**naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules**

| 10787R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 31.28 | 25.00 | [a] Naloxone Hydrochloride (DBL) [PF]<br>[a] NALOXONE SXP [XN] | [a] Naloxone Juno [JU] |

**naloxone hydrochloride 1 mg/mL injection, 2 mL syringe**

| 11077B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | 1 | 0 | 0.00 | 68.67 | 25.00 | Prenoxad [FF] |

**naloxone hydrochloride 1 mg/mL injection, 2 mL syringe**

| 11078C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | 1 | 0 | 0.00 | 68.67 | 25.00 | Prenoxad [FF] |

**naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation**

| 11816X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| DP | ‡1 | 0 | 0.00 | 65.78 | 25.00 | Nyxoid [MF] |

**naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation**

| 11817Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP MW | ‡1 | 0 | 0.00 | 65.78 | 25.00 | Nyxoid [MF] |

## *Drugs for treatment of hyperkalemia and hyperphosphatemia*

### LANTHANUM

**Authority Required (STREAMLINED)**

***5491***

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**lanthanum 500 mg chewable tablet, 2 x 45**

| 9403X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 190.50 | 25.00 | Fosrenol [TK] |

**lanthanum 750 mg chewable tablet, 6 x 15**

| 9404Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 282.89 | 25.00 | Fosrenol [TK] |

**lanthanum 1 g chewable tablet, 6 x 15**

| 9405B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 317.28 | 25.00 | Fosrenol [TK] |

### LANTHANUM

**Authority Required (STREAMLINED)**

***14872***

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**lanthanum 500 mg chewable tablet, 2 x 45**

| 14060B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *371.64 | 25.00 | Fosrenol [TK] |

**lanthanum 750 mg chewable tablet, 6 x 15**

| 13986D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *556.42 | 25.00 | Fosrenol [TK] |

**lanthanum 1 g chewable tablet, 6 x 15**

| 13874F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *625.20 | 25.00 | Fosrenol [TK] |

## PATIROMER

**Note** Special Pricing Arrangements apply.

**Authority Required (STREAMLINED)**

***14327***

Chronic hyperkalaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be in place of emergency treatment of hyperkalaemia, **AND**
- Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor.

**Treatment criteria:**

- Patient must not be undergoing dialysis.

**patiromer 8.4 g powder for oral liquid, 30 sachets**

| 13609G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 366.26 | 25.00 | Veltassa [CS] |

**patiromer 16.8 g powder for oral liquid, 30 sachets**

| 13613L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 366.26 | 25.00 | Veltassa [CS] |

## PATIROMER

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Special Pricing Arrangements apply.

**Authority Required**

***14342***

Chronic hyperkalaemia

Treatment Phase: Initial PBS-subsidised treatment (including grandfathered patients)

**Population criteria:**

- Patient must have stage 3 to stage 4 chronic kidney disease.

**Clinical criteria:**

- The condition must be inadequately controlled by a low potassium diet., **AND**
- Patient must have experienced at least 2 episodes of hyperkalaemia (defined as serum potassium levels of at least 6.0 mmol/L) within the 12 months prior to commencing this drug, **AND**
- The treatment must not be in place of emergency treatment of hyperkalaemia, **AND**
- Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor; **OR**
- Patient must be indicated for treatment with a renin angiotensin aldosterone system inhibitor, but unable to tolerate this due to prior occurrence of hyperkalaemia.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner with experience in the diagnosis and management of chronic kidney disease.

**patiromer 8.4 g powder for oral liquid, 30 sachets**

| 13610H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 366.26 | 25.00 | Veltassa [CS] |

**patiromer 16.8 g powder for oral liquid, 30 sachets**

| 13620W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 366.26 | 25.00 | Veltassa [CS] |

## SEVELAMER

**Note** Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

**Authority Required (STREAMLINED)**

***5491***

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sevelamer hydrochloride 800 mg tablet, 180**

| 2142R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 183.28 | 25.00 | [a] Renagel [GZ] | [a] Sevelamer Waymade [IX] |

**sevelamer carbonate 800 mg tablet, 180**

| 11856B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 161.31 | 25.00 | [a] ARX-SEVELAMER [XT] | [a] Sevelamer Lupin [GQ] |

## SEVELAMER

**Note** Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

**Authority Required (STREAMLINED)**

***14872***

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sevelamer hydrochloride 800 mg tablet, 180**

| 13934J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *357.20 | 25.00 | [a] Renagel [GZ] | [a] Sevelamer Waymade [IX] |

**sevelamer carbonate 800 mg tablet, 180**

| 14027G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *313.26 | 25.00 | [a] ARX-SEVELAMER [XT] | [a] Sevelamer Lupin [GQ] |

## SUCROFERRIC OXYHYDROXIDE

**Authority Required (STREAMLINED)**

***5491***

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90**

| 10250L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 381.71 | 25.00 | Velphoro [CS] |

## SUCROFERRIC OXYHYDROXIDE

**Authority Required (STREAMLINED)**

***14872***

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

### sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90

| 13985C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *754.06 | 25.00 | Velphoro [CS] |

## *Detoxifying agents for antineoplastic treatment*

## FOLINIC ACID

### folinic acid 50 mg/5 mL injection, 5 mL vial

| 8740B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|---|
| | 10 | 2 | 0.00 | *222.94 | 25.00 | [a] CALCIUM FOLINATE MEDSURGE [DZ] | [a] DBL Leucovorin Calcium [PF] |

## FOLINIC ACID

**Restricted benefit**

***5938***

Megaloblastic anaemias

**Clinical criteria:**

- The condition must be a result of folic acid deficiency from the use of folic acid antagonists.

### folinic acid 15 mg tablet, 10

| 2308L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 0 | 0.00 | 93.63 | 25.00 | Leucovorin Calcium (Hospira Pty Limited) [PF] |

## MESNA

**Restricted benefit**

***5106***

Urothelial toxicity

Treatment Phase: Prophylaxis or reduction of toxicity

**Clinical criteria:**

- The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

### mesna 400 mg/4 mL injection, 15 x 4 mL ampoules

| 8078E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 68.32 | 25.00 | Uromitexan [BX] |

### mesna 1 g/10 mL injection, 15 x 10 mL ampoules

| 8079F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| | 1 | 5 | 0.00 | 137.67 | 25.00 | Uromitexan [BX] |

## *Drugs for treatment of hypercalcemia*

## PHOSPHORUS

**Authority Required (STREAMLINED)**

***5089***

Hypophosphataemic rickets

**Authority Required (STREAMLINED)**

***5114***

Vitamin D-resistant rickets

**Authority Required (STREAMLINED)**

***5095***

Familial hypophosphataemia

**Authority Required (STREAMLINED)**

***5123***

Hypercalcaemia

**phosphorus 500 mg effervescent tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2946C NP | 1 | 5 | 0.00 | 80.68 | 25.00 | PHOSPHATE PHEBRA [FG] |

## PHOSPHORUS

**Authority Required (STREAMLINED)**

***14874***

Hypophosphataemic rickets

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required (STREAMLINED)**

***14962***

Vitamin D-resistant rickets

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required (STREAMLINED)**

***14921***

Familial hypophosphataemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**Authority Required (STREAMLINED)**

***14922***

Hypercalcaemia

**Clinical criteria:**

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

**phosphorus 500 mg effervescent tablet, 100**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13850Y NP | 2 | 5 | 0.00 | *148.64 | 25.00 | PHOSPHATE PHEBRA [FG] |

## *Other therapeutic products*

## POLYLACTIC ACID

**Authority Required**

***5087***

Severe facial lipoatrophy

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**polylactic acid 150 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9475Q | 2 | 4 | 0.00 | *280.98 | 25.00 | Sculptra [GA] |

## POLYLACTIC ACID

**Authority Required**

***5122***

Severe facial lipoatrophy

Treatment Phase: Maintenance PBS-subsidised treatment

**Clinical criteria:**

- The treatment must be for facial administration only, **AND**
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.

**Note** Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**polylactic acid 150 mg injection, 1 vial**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9476R | 2 | 0 | 0.00 | *280.98 | 25.00 | Sculptra [GA] |

# DIAGNOSTIC AGENTS

## URINE TESTS

### GLUCOSE AND KETONE INDICATOR URINE

**Restricted benefit**

***5852***

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

**glucose and ketone indicator urine diagnostic strip, 50**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3107M NP | 2 | 2 | 0.00 | *22.08 | 23.62 | Keto-Diastix [DX] |

# GENERAL NUTRIENTS

## OTHER NUTRIENTS

### MEDIUM CHAIN TRIGLYCERIDES

**Authority Required (STREAMLINED)**

***6181***

Chylous ascites

**Authority Required (STREAMLINED)**

***6134***

Chylothorax

**Authority Required (STREAMLINED)**

***6164***

Fat malabsorption

**Clinical criteria:**

- The condition must be due to liver disease; **OR**
- The condition must be due to short gut syndrome; **OR**
- The condition must be due to cystic fibrosis; **OR**
- The condition must be due to gastrointestinal disorders.

**Authority Required (STREAMLINED)**

***6203***

Hyperlipoproteinaemia type 1

**Authority Required (STREAMLINED)**

***6155***

Intractable childhood epilepsy

**Clinical criteria:**

- Patient must require a ketogenic diet.

**Authority Required (STREAMLINED)**

***6135***

Cerebrospinal fluid glucose transporter defect

**Clinical criteria:**

- Patient must require a ketogenic diet.

**Authority Required (STREAMLINED)**

***6146***

Long chain fatty acid oxidation disorders

**medium chain triglycerides oral liquid, 250 mL bottle**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9327X NP | 8 | 5 | 0.00 | *166.60 | 25.00 | Liquigen [SB] |

**medium chain triglycerides oral oil, 500 mL**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3128P NP | 2 | 5 | 0.00 | *112.40 | 25.00 | MCT Oil [SB] |

## PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS AND MINERALS

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

***6890***

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; **OR**
- Patient must have fat malabsorption due to short gut syndrome; **OR**
- Patient must have fat malabsorption due to cystic fibrosis; **OR**
- Patient must have fat malabsorption due to gastrointestinal disorders.

**Population criteria:**

- Patient must be aged from 1 to 10 years inclusive.

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**protein formula with carbohydrate, fat, vitamins and minerals oral liquid, 12 x 500 mL bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11939J NP | 7 | 5 | 0.00 | *1,593.06 | 25.00 | Nutrini Peptisorb Energy [NU] |

### *Fat/carbohydrates/proteins/minerals/vitamins, combinations*

## AMINO ACID SYNTHETIC FORMULA

**Authority Required**

***4368***

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority Required**

***4414***

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**amino acid synthetic formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 1521C NP | 12 | 5 | 0.00 | *427.32 | 25.00 | Neocate Junior Vanilla [SB] |

**amino acid synthetic formula powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2250K NP | 12 | 5 | 0.00 | *427.32 | 25.00 | EleCare [AB] |

## AMINO ACID SYNTHETIC FORMULA

**Authority Required**

***4323***

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***4352***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***4305***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***4312***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**amino acid synthetic formula powder for oral liquid, 400 g**

| 1180D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *287.96 | 25.00 | Neocate Junior Vanilla [SB] |

**amino acid synthetic formula powder for oral liquid, 400 g**

| 8574G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *287.96 | 25.00 | EleCare [AB] |

## AMINO ACID SYNTHETIC FORMULA

**Authority Required**

***4330***

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4337***

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4345***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4338***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4339***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4415***

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; **OR**
- Patient must have been receiving parenteral nutrition.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid synthetic formula powder for oral liquid, 400 g**

| 1192R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *287.96 | 25.00 | Neocate Junior Vanilla [SB] |

**amino acid synthetic formula powder for oral liquid, 400 g**

| 8575H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *287.96 | 25.00 | EleCare [AB] |

## AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Authority Required**

***4323***

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4352***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4305***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4312***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

| 2246F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *308.52 | 25.00 | Neocate LCP [SB] |

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

| 9339M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *230.36 | 25.00 | EleCare LCP [AB] |

## AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Authority Required**

***4330***

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4337***

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4345***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4338***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4339***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4415***

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; **OR**
- Patient must have been receiving parenteral nutrition.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

| 2560R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *308.52 | 25.00 | Neocate LCP [SB] |

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

| 9340N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *230.36 | 25.00 | EleCare LCP [AB] |

## AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Authority Required**

***4368***

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority Required**

***4414***

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

### amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

1545H

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 12 | 5 | 0.00 | *458.04 | 25.00 | Neocate Gold [SB] |

NP

## AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Authority Required**

***4323***

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4352***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***4305***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***4312***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

| 5466Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *308.52 | 25.00 | Neocate Gold [SB] |

## AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Authority Required**

***4323***

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***4352***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***4305***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***4312***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required**

***5945***

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides with 2-fucosyllactose and lacto-N-neotetraose powder for oral liquid, 400 g**

| 13627F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *308.52 | 25.00 | Alfamino [NT] |

## AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Authority Required**

***4330***

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4337***

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4345***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4338***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4339***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4415***

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; **OR**
- Patient must have been receiving parenteral nutrition.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g**

5467R

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *308.52 | 25.00 | Neocate Gold [SB] |

## AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Authority Required**

***4337***

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4345***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4338***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4330***

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4339***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4415***

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; **OR**
- Patient must have been receiving parenteral nutrition.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***5974***

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides with 2-fucosyllactose and lacto-N-neotetraose powder for oral liquid, 400 g**

| 13615N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *308.52 | 25.00 | Alfamino [NT] |

## PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

**Authority Required (STREAMLINED)**

***6174***

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**

- Patient must be up to the age of 24 months.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***6193***

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

**Population criteria:**

- Patient must be up to the age of 24 months.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***6204***

Cows' milk protein enteropathy and intolerance to soy protein

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist must be documented in the patient's medical records

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***6137***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**

***6182***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist must be documented in the patient's medical records

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**
***6194***
Biliary atresia
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**
***6157***
Chronic liver failure with fat malabsorption
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**
***6205***
Chylous ascites
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**
***6195***
Cystic fibrosis
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**
***6158***
Enterokinase deficiency
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**
***6166***
Proven fat malabsorption
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**
***6148***
Severe diarrhoea of greater than 2 weeks duration

**Population criteria:**

- Patient must be aged less than 4 months.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

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**Authority Required (STREAMLINED)**
***6138***
Severe intestinal malabsorption including short bowel syndrome
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

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**protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 450 g**

8259Q

| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|
| 8 | 5 | 0.00 | *197.72 | 25.00 | Aptamil Gold+ Pepti-Junior [NU] |

NP

## TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

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**Restricted benefit**
***4660***
Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; **OR**
- Patient must have fat malabsorption due to short gut syndrome; **OR**

- Patient must have fat malabsorption due to cystic fibrosis; **OR**
- Patient must have fat malabsorption due to gastrointestinal disorders.

**triglycerides medium chain formula oral liquid, 12 x 500 mL bottles**

| 12948L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 12 | 5 | 0.00 | *1,561.20 | 25.00 | Nutrini Peptisorb [SB] |

**triglycerides medium chain formula powder for oral liquid, 400 g**

| 10154K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *258.44 | 25.00 | Peptamen Junior [NT] |

**triglycerides medium chain formula powder for oral liquid, 400 g**

| 10155L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *355.56 | 25.00 | Lipistart [VF] |

## TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**
***4651***
Hyperlipoproteinaemia type 1
**Restricted benefit**
***4659***
Long chain fatty acid oxidation disorders
**Restricted benefit**
***4652***
Chylous ascites
**Restricted benefit**
***4653***
Chylothorax

**triglycerides medium chain formula powder for oral liquid, 400 g**

| 1938B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *355.56 | 25.00 | Lipistart [VF] |

## TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Restricted benefit**
***4660***
Dietary management of conditions requiring a source of medium chain triglycerides
**Clinical criteria:**

- Patient must have fat malabsorption due to liver disease; **OR**
- Patient must have fat malabsorption due to short gut syndrome; **OR**
- Patient must have fat malabsorption due to cystic fibrosis; **OR**
- Patient must have fat malabsorption due to gastrointestinal disorders.

**Restricted benefit**
***4651***
Hyperlipoproteinaemia type 1
**Restricted benefit**
***4659***
Long chain fatty acid oxidation disorders
**Restricted benefit**
***4652***
Chylous ascites
**Restricted benefit**
***4653***
Chylothorax

**triglycerides medium chain formula powder for oral liquid, 400 g**

| 15380L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *393.32 | 25.00 | Monogen [SB] |

### *Carbohydrates*

## MODIFIED LONG CHAIN AMYLOPECTIN

**Restricted benefit**
***5561***

Glycogen storage disease

**modified long chain amylopectin powder for oral liquid, 30 x 60 g sachets**

| 9386B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *633.96 | 25.00 | Glycosade [VF] |

## *Amino acids/carbohydrates/minerals/vitamins, combinations*

### AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4323***

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority Required**

***4352***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority Required**

***4312***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority Required**

***4337***

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**

- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority Required**

***4345***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority Required**

***4339***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority Required**

***4330***

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

| 14797T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *363.96 | 25.00 | Essential Care Jr [QH] |

## AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Authority Required**

***4323***

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4352***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4305***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4312***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***5945***

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

| 10522T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *318.92 | 25.00 | Alfamino Junior [NT] |

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

| 11161K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *335.16 | 25.00 | Neocate Junior [SB] |

## AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Authority Required**

***4337***

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4345***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4338***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4339***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4330***

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4415***

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; **OR**
- Patient must have been receiving parenteral nutrition.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***5974***

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

| 10527C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *318.92 | 25.00 | Alfamino Junior [NT] |

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

| 11183N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *335.16 | 25.00 | Neocate Junior [SB] |

## *Milk substitutes*

### MILK POWDER SYNTHETIC LOW CALCIUM

**Restricted benefit**

***6208***

Hypercalcaemia

**Population criteria:**

- Patient must be under the age of 4 years.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**milk powder synthetic low calcium powder for oral liquid, 400 g**

| 3092R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *354.84 | 25.00 | Locasol [SB] |

***Other combinations of nutrients***

## AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Authority Required**

***4368***

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority Required**

***4414***

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

### amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g

| 11343B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 12 | 5 | 0.00 | *464.52 | 25.00 | Neocate Syneo [SB] |

## AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Authority Required**

***4323***

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4352***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4305***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***4312***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

| 11331J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *312.76 | 25.00 | Neocate Syneo [SB] |

## AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Authority Required**

***4330***

Cows' milk anaphylaxis

**Treatment criteria:**

- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**

- Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority Required**

***4337***

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4345***

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux, **AND**
- Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4338***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4339***

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**

- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**Authority Required**

***4415***

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; **OR**
- Patient must have been receiving parenteral nutrition.

**Note** A risk/benefit analysis prior to treatment, and continuous patient monitoring from a health care professional is required for the use of this product, for this indication.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g**

| 11340W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *312.76 | 25.00 | Neocate Syneo [SB] |

## AMINO ACID FORMULA WITH CARBOHYDRATE WITHOUT PHENYLALANINE

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

**Restricted benefit**
***4295***
Phenylketonuria

**amino acid formula with carbohydrate without phenylalanine modified release tablet, 6 x 77**

| 12072J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,255.64 | 25.00 | PKU Easy Tablet [OH] |

## AMINO ACID FORMULA WITH CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE

**Restricted benefit**
***4295***
Phenylketonuria

**amino acid formula with carbohydrate, vitamins, minerals and trace elements without phenylalanine powder for oral liquid, 30 x 20 g sachets**

| 10806R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *940.20 | 25.00 | PKU Go [OH] |

## AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT METHIONINE

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

**Restricted benefit**
***5534***
Pyridoxine non-responsive homocystinuria

**amino acid formula with fat, carbohydrate without methionine modified release tablet, 6 x 77**

| 12006X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 5 | 0.00 | *2,883.89 | 25.00 | HCU Easy Tablet [OH] |

## AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE

**Restricted benefit**
***5970***
Phenylketonuria

**amino acid formula with fat, carbohydrate without phenylalanine tablet: modified release, 4 x 110 g**

| 10683G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 7 | 5 | 0.00 | *1,778.35 | 25.00 | PKU Easy Microtabs [OH] |

## AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE AND TYROSINE

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

**Restricted benefit**
***5533***
Tyrosinaemia

**amino acid formula with fat, carbohydrate without phenylalanine and tyrosine modified release tablet, 6 x 77**

| 12015J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *2,329.00 | 25.00 | TYR Easy Tablet [OH] |

## AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT VALINE, LEUCINE AND ISOLEUCINE

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition

**Restricted benefit**
***5571***
Maple syrup urine disease

**amino acid formula with fat, carbohydrate without valine, leucine and isoleucine modified release tablet, 6 x 77**

| 12014H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 5 | 0.00 | *2,883.89 | 25.00 | MSUD Easy Tablet [OH] |

## AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS AND MINERALS WITHOUT PHENYLALANINE

**Restricted benefit**

***5970***

Phenylketonuria

**amino acid formula with fat, carbohydrate, vitamins and minerals without phenylalanine tablet: modified release, 6 x 100 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14782B NP | 7 | 5 | 0.00 | *1,753.08 | 25.00 | PKU Easy Microtabs Plus [OH] |

## AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE

**Restricted benefit**

***5970***

Phenylketonuria

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine oral liquid: powder for, 30 x 34 g bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10632N NP | 5 | 5 | 0.00 | *1,755.64 | 25.00 | PKU Easy Shake & Go [OH] |

## AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS, WITHOUT PHENYLALANINE AND TYROSINE

**Restricted benefit**

***5533***

Tyrosinaemia

**amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements, without phenylalanine and tyrosine powder for oral liquid, 30 x 34 g bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10934L NP | 4 | 5 | 0.00 | *2,888.12 | 25.00 | TYR Easy Shake & Go [OH] |

## AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Authority approval for an increased maximum quantity, up to 3 times the stated quantity (in packs), may be sought.

**Authority Required**

***4338***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority Required**

***4415***

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

- Patient must have failed to respond to protein hydrolysate formulae; **OR**
- Patient must have been receiving parenteral nutrition.

**Authority Required**

***5974***

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

- Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**Authority Required**

***5945***

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

- Patient must be 18 years of age or less.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority Required**

***4305***

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

| 14825G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *363.96 | 25.00 | Essential Care Jr [QH] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

**Restricted benefit**

***5323***

Proven glutaric aciduria type 1

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 400 g**

| 2650L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *648.28 | 25.00 | GA1 Anamix infant [SB] |

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 500 g**

| 10466W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 9 | 5 | 0.00 | *2,724.72 | 25.00 | XLYS, LOW TRY Maxamum [SB] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

**Restricted benefit**

***6007***

Proven glutaric aciduria type 1

**amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 18 g sachets**

| 10715Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *1,852.04 | 25.00 | GA1 Anamix Junior [NU] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

**Restricted benefit**

***5323***

Proven glutaric aciduria type 1

**Restricted benefit**

***11482***

Pyridoxine dependent epilepsy

**Clinical criteria:**

- Patient must be managed on a low lysine diet for pyridoxine dependent epilepsy, **AND**
- The condition must be treated by or in consultation with a metabolic physician.

**amino acid formula with vitamins and minerals without lysine and low in tryptophan containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets**

| 14781Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *1,852.04 | 25.00 | GA explore5 [VF] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

**Restricted benefit**

***5534***

Pyridoxine non-responsive homocystinuria

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 125 mL pouches**

| 1548L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *2,610.21 | 25.00 | HCU Lophlex LQ 20 [SB] |

**amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets**

| 2640Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *3,443.84 | 25.00 | HCU cooler 20 [VF] |

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 25 g sachets**

| 8744F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *2,610.24 | 25.00 | HCU express 15 [VF] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

**Restricted benefit**

***5559***

Pyridoxine non-responsive homocystinuria

**Population criteria:**

- Patient must be an infant or a very young child.

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 400 g**

| 8417B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *616.28 | 25.00 | HCU Anamix infant [SB] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

**Restricted benefit**

***6038***

Pyridoxine non-responsive homocystinuria

**amino acid formula with vitamins and minerals without methionine powder for oral liquid, 30 x 29 g sachets**

| 12273Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *3,443.84 | 25.00 | HCU Lophlex [SB] |

**amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 36 g sachets**

| 10693T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,759.96 | 25.00 | HCU Anamix Junior [NU] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE

**Restricted benefit**

***5560***

Methylmalonic acidaemia

**Restricted benefit**
***5542***
Propionic acidaemia

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 25 g sachets**

| 3443F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *2,610.24 | 25.00 | MMA/PA express 15 [VF] |

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 400 g**

| 8058D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *616.28 | 25.00 | MMA/PA Anamix infant [SB] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE

**Restricted benefit**
***6055***
Methylmalonic acidaemia
**Restricted benefit**
***5986***
Propionic acidaemia

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets**

| 14775P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *1,759.96 | 25.00 | MMA/PA explore5 [VF] |

**amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 18 g sachets**

| 10730R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *1,759.96 | 25.00 | MMA/PA Anamix Junior [NU] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

**Restricted benefit**
***4295***
Phenylketonuria

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL pouches**

| 9397N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *661.46 | 25.00 | PKU Lophlex LQ 10 [SB] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL pouches**

| 2382J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *827.40 | 25.00 | PKU Cooler 10 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL pouches**

| 9021T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,686.12 | 25.00 | PKU Lophlex LQ 20 [SB] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL pouches**

| 14290D | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,686.12 | 25.00 | PKU Lophlex Select LQ [NU] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL bottles**

| 9396M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,027.76 | 25.00 | PKU Anamix Junior LQ [SB] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL pouches**

| 8846N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,265.92 | 25.00 | PKU Cooler 15 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouches**

| 2474F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,706.28 | 25.00 | PKU Cooler 20 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouches**

| 10411Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,706.28 | 25.00 | PKU Air 20 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL**

| 8746H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 5 | 0.00 | *830.39 | 25.00 | Easiphen [SB] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 25 g sachets**

| 8591E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,266.64 | 25.00 | PKU express 15 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 28 g sachets**

| 12136R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,686.12 | 25.00 | PKU Lophlex [SB] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 34 g sachets**

| 1909L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,706.28 | 25.00 | PKU express 20 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets**

| 5483N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *847.08 | 25.00 | PKU squeezie [VF] |

**amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g tubs**

| 2806Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *1,527.27 | 25.00 | PKU Lophlex Sensation 20 [SB] |

**amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g**

| 2739E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *1,098.52 | 25.00 | XP Maxamum [SB] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

**Restricted benefit**

***4964***

Phenylketonuria

**Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 36 g sachets**

| 10258X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *848.12 | 25.00 | PKU Anamix Junior [SB] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

**Restricted benefit**

***5533***

Tyrosinaemia

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 125 mL pouches**

| 1547K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *2,051.79 | 25.00 | TYR Lophlex LQ 20 [SB] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL pouches**

| 2701E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *3,443.84 | 25.00 | TYR cooler 20 [VF] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 28 g sachets**

| 12274B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *3,443.84 | 25.00 | TYR Lophlex [SB] |

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 400 g**

| 8445L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *616.28 | 25.00 | TYR Anamix infant [SB] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

**Restricted benefit**

***4923***

Tyrosinaemia

**Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 36 g sachets**

| 10260B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,759.96 | 25.00 | TYR Anamix Junior [SB] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE, TYROSINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

**Restricted benefit**

***5533***

Tyrosinaemia

**amino acid formula with vitamins and minerals without phenylalanine, tyrosine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets**

| 14126L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *1,760.04 | 25.00 | TYR explore5 [VF] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

**Restricted benefit**

***5571***

Maple syrup urine disease

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 125 mL pouches**

| 1546J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 3 | 5 | 0.00 | *2,610.21 | 25.00 | MSUD Lophlex LQ 20 [SB] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL pouches**

| 2375B | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *2,610.24 | 25.00 | MSUD cooler 15 [VF] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches**

| 2654Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *3,443.84 | 25.00 | MSUD cooler 20 [VF] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 25 g sachets**

| 8632H | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *2,610.24 | 25.00 | MSUD express 15 [VF] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 30 x 28 g sachets**

| 12285N | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *3,443.84 | 25.00 | MSUD Lophlex [SB] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 400 g**

| 2380G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *616.28 | 25.00 | MSUD Anamix infant [SB] |

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 500 g**

| 8057C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *2,276.84 | 25.00 | MSUD Maxamum [SB] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

**Restricted benefit**

***4954***

Maple syrup urine disease

**Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 36 g sachets**

| 10259Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,759.96 | 25.00 | MSUD Anamix Junior [SB] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE, ISOLEUCINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

**Restricted benefit**

***5571***

Maple syrup urine disease

**amino acid formula with vitamins and minerals without valine, leucine, isoleucine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets**

| 14118C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *1,760.04 | 25.00 | MSUD explore5 [VF] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID

**Restricted benefit**

***4295***

Phenylketonuria

**amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 12.5 g sachets**

| 11185Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *940.20 | 25.00 | PKU Anamix First Spoon [SB] |

**amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 12.5 g sachets**

| 11859E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *940.20 | 25.00 | PKU Explore 5 [VF] |

**amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid powder for oral liquid, 30 x 25 g sachets**

| 11836Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *940.16 | 25.00 | PKU Explore 10 [VF] |

## AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT METHIONINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

**Restricted benefit**

***5534***

Pyridoxine non-responsive homocystinuria

**amino acid formula with vitamins and minerals, without methionine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets**

| 14114W | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *1,760.04 | 25.00 | HCU explore5 [VF] |

## AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE

**Restricted benefit**

***4295***

Phenylketonuria

**amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine powder for oral liquid, 400 g**

| 8479G | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *563.96 | 25.00 | PKU Anamix infant [SB] |

**amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine powder for oral liquid, 4 x 400 g**

| 14239K | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 2 | 5 | 0.00 | *599.34 | 25.00 | PKU Start [VF] |

## AMINO ACID FORMULA WITHOUT PHENYLALANINE

**Restricted benefit**

***4295***

Phenylketonuria

**amino acid formula without phenylalanine 1 g tablet, 75**

| 8678R | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 24 | 5 | 0.00 | *1,162.20 | 25.00 | Phlexy-10 [SB] |

## AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE

**Restricted benefit**

***5571***

Maple syrup urine disease

**amino acid formula without valine, leucine and isoleucine containing 5 g of protein equivalent powder for oral liquid, 30 x 6 g sachets**

| 10161T | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 12 | 5 | 0.00 | *2,888.16 | 25.00 | MSUD amino5 [VF] |

## ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE

**Restricted benefit**

***6141***

Peroxisomal biogenesis disorders

**arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid powder for oral liquid, 30 x 4 g sachets**

| 10036F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *327.76 | 25.00 | keyomega [VF] |

## ARGININE WITH CARBOHYDRATE

**Restricted benefit**

***4555***

Urea cycle disorders

**Note** Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

**arginine with carbohydrate containing 500 mg arginine powder for oral liquid, 30 x 4 g sachets**

| 9437Q | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *436.08 | 25.00 | Arginine 500 [VF] |

**arginine with carbohydrate containing 2 g arginine powder for oral liquid, 30 x 4 g sachets**

| 5482M | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *649.44 | 25.00 | Arginine 2000 [VF] |

**arginine with carbohydrate containing 5 g arginine powder for oral liquid, 30 x 7.6 g sachets**

| 10093F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *860.76 | 25.00 | Arginine 5000 [VF] |

## CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS

**Restricted benefit**

***4438***

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**carbohydrate, fat, vitamins, minerals and trace elements powder for oral liquid, 400 g**

| 8369L | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *252.36 | 25.00 | Energivit [SB] |

## CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

**Restricted benefit**

***4438***

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 200 kilocalories powder for oral liquid, 30 x 43 g sachets**

| 10039J | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *420.96 | 25.00 | basecal 200 [VF] |

## CITRULLINE

**Restricted benefit**

***5984***

Urea cycle disorders

**Clinical criteria:**

- The treatment must be for preventing low plasma arginine levels; **OR**
- The treatment must be for preventing low citrulline levels.

**Note** Citrulline is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism

**citrulline 1 g tablet, 300**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10736C NP | ‡1 | 5 | 0.00 | 1,079.11 | 25.00 | Citrulline Easy [OH] |

## CITRULLINE WITH CARBOHYDRATE

**Restricted benefit**

***6683***

Urea cycle disorders

**Clinical criteria:**

- The treatment must be for preventing low plasma arginine levels; **OR**
- The treatment must be for preventing low citrulline levels.

**Note** Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

**citrulline with carbohydrate containing 1 g citrulline powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 5481L NP | 4 | 5 | 0.00 | *436.08 | 25.00 | Citrulline 1000 [VF] |

## ESSENTIAL AMINO ACIDS FORMULA

**Restricted benefit**

***4925***

Gyrate atrophy of the choroid and retina

**Restricted benefit**

***4958***

Urea cycle disorders

**essential amino acids formula powder for oral liquid, 2 x 200 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9329B NP | 6 | 5 | 0.00 | *1,018.98 | 25.00 | Essential Amino Acid Mix [SB] |

## ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C

**Restricted benefit**

***4925***

Gyrate atrophy of the choroid and retina

**Restricted benefit**

***4958***

Urea cycle disorders

**essential amino acids formula with minerals and vitamin C powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2027Q NP | 5 | 5 | 0.00 | *508.74 | 25.00 | Dialamine [SB] |

## ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS

**Restricted benefit**

***4925***

Gyrate atrophy of the choroid and retina

**Restricted benefit**

***4958***

Urea cycle disorders

**essential amino acids formula with vitamins and minerals powder for oral liquid, 30 x 12.5 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13759E NP | 6 | 5 | 0.00 | *1,174.02 | 25.00 | EAA Supplement [VF] |

## GLYCINE WITH CARBOHYDRATE

**Restricted benefit**

***4704***

Isovaleric acidaemia

**glycine with carbohydrate containing 500 mg glycine powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10195N | | | | | | |
| NP | 4 | 5 | 0.00 | *459.76 | 25.00 | Glycine500 [VF] |

## GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACID FORMULA WITH VITAMINS, MINERALS, AND LOW IN TYROSINE AND PHENYLALANINE

**Restricted benefit**

***5533***

Tyrosinaemia

**glycomacropeptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine powder for oral liquid, 30 x 31 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12175T | | | | | | |
| NP | 4 | 5 | 0.00 | *3,277.12 | 25.00 | Tylactin Build 20 [QH] |

**glycomacropeptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine powder for oral liquid, 30 x 35 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11832R | | | | | | |
| NP | 4 | 5 | 0.00 | *4,009.36 | 25.00 | TYR Sphere20 [VF] |

## GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Restricted benefit**

***4295***

Phenylketonuria

**glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 60 x 20 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11084J | | | | | | |
| NP | 5 | 5 | 0.00 | *1,315.79 | 25.00 | PKU Restore [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 40 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13714T | | | | | | |
| NP | 4 | 5 | 0.00 | *2,366.84 | 25.00 | Camino Pro Bettermilk [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2644E | | | | | | |
| NP | 14 | 5 | 0.00 | *1,932.28 | 25.00 | Camino Pro Complete [QH] |

## GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Restricted benefit**

***5012***

Phenylketonuria

**Note** This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10332T | | | | | | |
| NP | 4 | 5 | 0.00 | *2,366.76 | 25.00 | PKU Glytactin RTD 15 [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11640P | | | | | | |
| NP | 4 | 5 | 0.00 | *2,366.76 | 25.00 | PKU Glytactin RTD 15 Lite [QH] |

## GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Restricted benefit**

***5533***

Tyrosinaemia

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10528D | | | | | | |
| NP | 4 | 5 | 0.00 | *3,034.36 | 25.00 | Tylactin RTD [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent bar, 14 x 81 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11290F | | | | | | |
| NP | 8 | 5 | 0.00 | *2,839.40 | 25.00 | Tylactin Complete [QH] |

## GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

**Restricted benefit**

***4295***

Phenylketonuria

**Note** This product is low in folic acid, choline and methionine and is not intended as a sole source of nutrition.

**glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g of protein equivalent powder for oral liquid, 30 x 15 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14820B | | | | | | |
| NP | 4 | 5 | 0.00 | *1,577.04 | 25.00 | PKU Build 10 [QH] |

**glycomacropeptide and essential amino acids with vitamins and minerals containing 20 g of protein equivalent powder for oral liquid, 30 x 32 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11279P | | | | | | |
| NP | 4 | 5 | 0.00 | *3,119.28 | 25.00 | PKU Build 20 [QH] |

## GLYCOMACROPEPTIDE FORMULA WITH AMINO ACIDS AND LOW PHENYLALANINE

**Note** This product does not contain any vitamins, is low in mineral content and is not intended as a sole source of nutrition.

**Restricted benefit**

***4295***

Phenylketonuria

**glycomacropeptide formula with amino acids and low phenylalanine powder for oral liquid, 30 x 12.5 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14650C | | | | | | |
| NP | 5 | 5 | 0.00 | *1,315.79 | 25.00 | PKU GMPro MIX-IN [SB] |

## GLYCOMACROPEPTIDE FORMULA WITH AMINO ACIDS, VITAMINS, MINERALS, TRACE ELEMENTS, CARBOHYDRATE, FAT AND LOW PHENYLALANINE

**Restricted benefit**

***4295***

Phenylketonuria

**glycomacropeptide formula with amino acids, vitamins, minerals, trace elements, carbohydrate, fat and low phenylalanine powder for oral liquid, 30 x 33.4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 14644R | | | | | | |
| NP | 4 | 5 | 0.00 | *2,115.96 | 25.00 | PKU GMPro ULTRA [SB] |

## GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE

**Restricted benefit**

***4295***

Phenylketonuria

**glycomacropeptide formula with docosahexaenoic acid and low phenylalanine oral liquid, 15 x 237 mL bottles**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 13257R | | | | | | |
| NP | 8 | 5 | 0.00 | *2,010.92 | 25.00 | PKU Sphere Liquid [VF] |

**glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 35 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11071Q | | | | | | |
| NP | 4 | 5 | 0.00 | *2,010.96 | 25.00 | PKU Sphere20 [VF] |

**glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 40 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 15536Q | | | | | | |
| NP | 4 | 5 | 0.00 | *2,010.96 | 25.00 | PKU GMPro Delight [SB] |

## GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE

**Restricted benefit**

***5012***

Phenylketonuria

**Note** This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

**glycomacropeptide formula with docosahexaenoic acid and low phenylalanine oral liquid, 18 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11844J | | | | | | |
| NP | 10 | 5 | 0.00 | *1,510.54 | 25.00 | PKU GMPro LQ [SB] |

## HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Restricted benefit**

***4253***

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; **OR**
- Patient must have a glucose transport protein defect; **OR**
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 3: 1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) powder for oral liquid, 300 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 2652N | | | | | | |
| NP | 24 | 5 | 0.00 | *817.56 | 25.00 | KetoCal 3:1 [SB] |

## HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Restricted benefit**

***4289***

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; **OR**
- Patient must have a glucose transport protein defect; **OR**
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4: 1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydate plus protein) powder for oral liquid, 300 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9446E | | | | | | |
| NP | 24 | 5 | 0.00 | *857.16 | 25.00 | KetoCal 4:1 [SB] |

## HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Restricted benefit**

***4709***

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; **OR**
- Patient must have a glucose transport protein defect; **OR**
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4: 1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**Note** Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid, 32 x 200 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 10185C | | | | | | |
| NP | 5 | 5 | 0.00 | *921.64 | 25.00 | KetoCal 4:1 LQ [SB] |

## HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Restricted benefit**

***12096***

Ketogenic diet

**Treatment criteria:**

- Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of: (i) a metabolic physician, (ii) a neurologist.

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; **OR**
- Patient must have a glucose transport protein defect; **OR**
- Patient must have pyruvate dehydrogenase deficiency.

**Note** Requests seeking an increased maximum quantity (packs) up to 4 times that stated, may be authorised.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 36 x 100 g tubs**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12635B NP | 4 | 5 | 0.00 | *772.16 | 25.00 | K.Yo [VF] |

## HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorisation for an increased maximum quantity, up to double the stated 'Max qty packs' value, may be sought.

**Restricted benefit**

***11644***

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; **OR**
- Patient must have a glucose transport protein defect; **OR**
- Patient must have pyruvate dehydrogenase deficiency.

**Treatment criteria:**

- Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of: (i) a metabolic physician, (ii) a neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio medium chain fat to carbohydrate plus protein) oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12456N NP | 6 | 5 | 0.00 | *1,607.04 | 25.00 | KetoVie 4:1 [QH] |

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio medium chain fat to carbohydrate plus protein) oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12464B NP | 6 | 5 | 0.00 | *1,075.44 | 25.00 | KetoVie 3:1 [QH] |

## HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorisation for an increased maximum quantity, up to double the stated 'Max qty packs' value, may be sought.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority Required**

***12459***

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; **OR**
- Patient must have a glucose transport protein defect; **OR**
- Patient must have pyruvate dehydrogenase deficiency, **AND**
- Patient must have severe intestinal malabsorption of whole protein ketogenic diet formula, **AND**
- Patient must have unsuccessfully trialled at least one of the PBS-listed products with the indication of: 'Ketogenic diet'.

This product must only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio medium chain fat to carbohydrate plus protein) oral liquid, 30 x 250 mL cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 12789D NP | 6 | 5 | 0.00 | *1,828.56 | 25.00 | KetoVie Peptide 4:1 [QH] |

## ISOLEUCINE WITH CARBOHYDRATE

**Restricted benefit**

***5571***

Maple syrup urine disease

**isoleucine with carbohydrate containing 50 mg isoleucine powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9134R NP | 4 | 5 | 0.00 | *436.08 | 25.00 | Isoleucine 50 [VF] |

**isoleucine with carbohydrate containing 1 g isoleucine powder for oral liquid, 30 x 4 g sachets**

| 9436P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *478.76 | 25.00 | Isoleucine 1000 [VF] |

## MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

**Restricted benefit**

***6658***

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; **OR**
- Patient must have a glucose transport protein defect; **OR**
- Patient must have pyruvate dehydrogenase deficiency; **OR**
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

**milk protein and fat formula with vitamins and minerals carbohydrate free powder for oral liquid, 225 g**

| 8630F | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 24 | 5 | 0.00 | *889.80 | 25.00 | Carbohydrate Free Mixture [SB] |

## PHENYLALANINE WITH CARBOHYDRATE

**Restricted benefit**

***5533***

Tyrosinaemia

**phenylalanine with carbohydrate containing 50 mg phenylalanine powder for oral liquid, 30 x 4 g sachets**

| 9384X | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *436.08 | 25.00 | Phenylalanine 50 [VF] |

## PROTEIN FORMULA WITH AMINO ACIDS, CARBOHYDRATES, VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

**Restricted benefit**

***5970***

Phenylketonuria

**protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid oral liquid, 30 x 130 mL pouches**

| 10658Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 5 | 5 | 0.00 | *1,754.69 | 25.00 | PKU Easy [OH] |

## PROTEIN FORMULA WITH VITAMINS AND MINERALS, AND LOW IN POTASSIUM, PHOSPHORUS, CALCIUM, CHLORIDE AND VITAMIN A

**Authority Required (STREAMLINED)**

***11070***

Chronic renal failure

**Population criteria:**

- Patient must be a child aged 3 years or older.

**Clinical criteria:**

- Patient must require treatment with a low protein and a low phosphorus diet; **OR**
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**protein formula with vitamins and minerals, and low in potassium, phosphorus, calcium, chloride and vitamin A oral liquid, 24 x 125 mL bottles**

| 12191P | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 8 | 5 | 0.00 | *1,327.88 | 25.00 | Renastep [VF] |

## SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

**Restricted benefit**

***6658***

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; **OR**
- Patient must have a glucose transport protein defect; **OR**
- Patient must have pyruvate dehydrogenase deficiency; **OR**
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

**soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 384 mL can**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 8577K NP | 120 | 5 | 0.00 | *545.64 | 25.00 | RCF [AB] |

## TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER

**Restricted benefit**

***4438***

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**triglycerides long chain with glucose polymer oral liquid, 6 x 1 L cartons**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9309Y NP | 4 | 5 | 0.00 | *693.56 | 25.00 | ProZero [VF] |

## TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER

**Restricted benefit**

***4438***

Proven inborn errors of protein metabolism

**Clinical criteria:**

- Patient must be unable to meet their energy requirements with permitted food and formulae.

**triglycerides medium chain and long chain with glucose polymer powder for oral liquid, 400 g**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 3136C NP | 8 | 5 | 0.00 | *233.64 | 25.00 | Duocal [SB] |

## TYROSINE WITH CARBOHYDRATE

**Restricted benefit**

***4295***

Phenylketonuria

**Note** This formulation is suitable for patients aged 3 and older.

**tyrosine with carbohydrate containing 1 g tyrosine powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9165J NP | 4 | 5 | 0.00 | *436.08 | 25.00 | Tyrosine 1000 [VF] |

## VALINE WITH CARBOHYDRATE

**Restricted benefit**

***5571***

Maple syrup urine disease

**valine with carbohydrate containing 50 mg valine powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9135T NP | 4 | 5 | 0.00 | *436.08 | 25.00 | Valine 50 [VF] |

**valine with carbohydrate containing 1 g valine powder for oral liquid, 30 x 4 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 9434M NP | 4 | 5 | 0.00 | *478.76 | 25.00 | Valine 1000 [VF] |

## VITAMINS, MINERALS AND TRACE ELEMENTS

**Restricted benefit**

***7275***

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be aged 3 years or older.

**Note** Phlexy-Vits must only be used under strict supervision of a dietician and a paediatrician.

**vitamins, minerals and trace elements powder for oral liquid, 30 x 7 g sachets**

| | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| 11200L NP | 1 | 5 | 0.00 | 274.97 | 25.00 | Phlexy-Vits [SB] |

## VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

**Restricted benefit**

***6152***

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be an infant or a child.

**Note** Paediatric Seravit must only be used under strict supervision of a dietitian and a paediatrician.

**vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 200 g**

| 9328Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 6 | 5 | 0.00 | *328.08 | 25.00 | Paediatric Seravit [SB] |

## VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

**Restricted benefit**

***6159***

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be aged 3 years or older.

**Note** FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.

**vitamins, minerals and trace elements with carbohydrate powder for oral liquid, 30 x 6 g sachets**

| 10149E | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 1 | 5 | 0.00 | 248.41 | 25.00 | FruitiVits [VF] |

## WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE

**Authority Required (STREAMLINED)**

***6190***

Chronic renal failure

**Population criteria:**

- Patient must be an infant or a young child.

**Clinical criteria:**

- Patient must require treatment with a low protein and a low phosphorus diet; **OR**
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose powder for oral liquid, 6 x 400 g cans**

| 2870C | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 4 | 5 | 0.00 | *1,364.44 | 25.00 | Renastart [VF] |

## WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE

**Authority Required (STREAMLINED)**

***6190***

Chronic renal failure

**Population criteria:**

- Patient must be an infant or a young child.

**Clinical criteria:**

- Patient must require treatment with a low protein and a low phosphorus diet; **OR**
- Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose powder for oral liquid, 400 g**

| 8587Y | Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
|---|---|---|---|---|---|---|
| NP | 16 | 5 | 0.00 | *853.40 | 25.00 | Kindergen [SB] |

# Extemporaneously Prepared Benefits

# Drug Tariff

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL<br>$ | 1 g/mL<br>$ | 10 g/mL<br>$ | 100 g/mL<br>$ |
| Acacia, powdered | BP | 0.08 | 0.84 | 7.60 | 48.25 |
| Acetic Acid (33 per cent) | BP | 0.02 | 0.21 | 2.09 | 20.91 |
| Acetic Acid (6 per cent) | BP | 0.01 | 0.05 | 0.48 | 4.79 |
| Acetone (use as additive only) | BP | 0.04 | 0.43 | 3.85 | 34.25 |
| Alum | BP | 0.09 | 0.93 | 8.34 | 74.10 |
| Aluminium Acetate Solution | BP | 0.02 | 0.23 | 2.05 | 18.21 |
| Anise Water Concentrated 1 in 40 | BP | 0.01 | 0.09 | 0.87 | 8.68 |
| Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.01 | 0.07 | 0.59 | 5.26 |
| Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures) | BP | 0.19 | 1.86 | 16.74 | 106.28 |
| Aspirin | BP | 0.50 | 4.97 | 44.76 | 397.87 |
| Belladonna Tincture | BP | 0.40 | 3.96 | 35.66 | 317.02 |
| Benzocaine | BP | 0.33 | 3.28 | 18.76 | 187.60 |
| Benzoic Acid | BP | 0.13 | 1.30 | 11.71 | 74.38 |
| Benzoic Acid Compound Ointment | APF | 0.03 | 0.26 | 2.35 | 20.86 |
| Benzoic Acid Solution | BP | 0.02 | 0.25 | 2.48 | 24.82 |
| Benzoin Compound Tincture | BP | 0.06 | 0.62 | 5.56 | 49.46 |
| Boric Acid (use as additive only) | BP | 0.04 | 0.39 | 3.52 | 22.32 |
| Boric Acid, Olive Oil and Zinc Oxide Ointment | QHF | 0.02 | 0.23 | 2.07 | 13.17 |
| Calcium Hydroxide | BP | 0.28 | 2.78 | 24.99 | 158.67 |
| Calcium Hydroxide Solution | BP | 0.01 | 0.04 | 0.40 | 3.97 |
| Castor Oil (use as additive only) | BP | 0.02 | 0.22 | 1.97 | 17.51 |
| Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.01 | 0.06 | 0.50 | 4.44 |
| Cetrimide Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.01 | 0.13 | 1.17 | 10.42 |
| Chlorhexidine Acetate (use as additive only) | BP | 0.78 | 7.79 | 44.53 | 445.30 |
| Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients) | APF | 0.01 | 0.06 | 0.52 | 4.60 |
| Chloroform (use as additive only) | BP | 0.08 | 0.80 | 7.19 | 63.90 |
| Chloroform Spirit | BP | 0.01 | 0.09 | 0.89 | 8.94 |
| Chloroform Water Concentrated 1 in 40 | APF 15 | 0.01 | 0.11 | 1.07 | 10.67 |
| Citric Acid Monohydrate | BP | 0.15 | 1.48 | 13.28 | 84.32 |
| Coal Tar | BP | 0.06 | 0.56 | 5.00 | 44.45 |

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL $ | 1 g/mL $ | 10 g/mL $ | 100 g/mL $ |
| Coal Tar Solution | BP | 0.10 | 1.00 | 9.01 | 57.23 |
| Cocaine Hydrochloride | BP | 158.22 | 1582.19 | 9041.10 | 90411.00 |
| Coconut Oil | BP | 0.07 | 0.72 | 6.48 | 41.16 |
| Codeine Linctus | APF | 0.02 | 0.20 | 1.79 | 11.34 |
| Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children) | BP | 7.12 | 71.17 | 406.68 | 4066.80 |
| Collodion Flexible | BP | 0.68 | 6.84 | 61.55 | 390.81 |
| Dithranol | BP | 6.19 | 61.89 | 353.67 | 3536.70 |
| Emulsifying Ointment (for use only as a base combined with active ingredients) | BP | 0.01 | 0.15 | 1.32 | 11.76 |
| Ephedrine Hydrochloride (may only be prescribed in nasal instillations) | BP | 3.82 | 38.17 | 343.53 | 2181.12 |
| Ethanol (90 per cent) (use as additive only) | BP | 0.01 | 0.07 | 0.59 | 5.20 |
| Ethanol (96 per cent) (use as additive only) | BP | 0.01 | 0.09 | 0.79 | 7.06 |
| Ether Solvent (use as additive only) | BP | 0.29 | 2.35 | 18.83 | 167.36 |
| Eucalyptus Oil (use as additive only) | BP | 0.02 | 0.18 | 1.63 | 14.49 |
| Ferrous Sulfate | BP | 0.11 | 1.12 | 10.09 | 64.04 |
| Formaldehyde Solution | BP | 0.09 | 0.94 | 8.48 | 75.39 |
| Gentian Alkaline Mixture | APF | 0.01 | 0.09 | 0.68 | 6.00 |
| Glycerol | BP | 0.02 | 0.22 | 1.96 | 17.43 |
| Honey Purified (use as additive only) | BP 1993 | 0.01 | 0.03 | 0.27 | 2.44 |
| Hydroxybenzoate Compound Solution | APF | 0.09 | 0.68 | 5.42 | 48.17 |
| Iodine | BP | 1.83 | 18.29 | 104.49 | 1044.87 |
| Iodine Alcoholic Solution | BP | 0.04 | 0.42 | 3.77 | 23.95 |
| Iodine Aqueous Oral Solution | BP | 0.07 | 0.67 | 6.01 | 38.16 |
| Kaolin Mixture | BPC 1968 | 0.04 | 0.39 | 3.49 | 31.03 |
| Kaolin and Opium Mixture | APF 14 | 0.01 | 0.10 | 0.82 | 7.27 |
| Lactic Acid | BP | 0.44 | 4.39 | 39.53 | 251.00 |
| Lavender Spike Oil | BPC 1968 | 0.13 | 1.29 | 11.57 | 73.44 |
| Liquorice Liquid Extract | BP | 0.19 | 1.86 | 16.71 | 148.51 |
| Magnesium Carbonate Light | BP | 0.05 | 0.37 | 2.92 | 25.99 |
| Magnesium Sulfate (may only be prescribed for other than oral use) | BP | 0.01 | 0.12 | 1.12 | 9.96 |
| Magnesium Trisilicate | BP | 0.06 | 0.62 | 5.54 | 49.26 |
| Menthol, Racemic or Levomenthol | BP | 0.33 | 3.30 | 29.72 | 188.68 |
| Methyl Hydroxybenzoate | BP | 0.45 | 4.52 | 40.65 | 258.08 |
| Methyl Hydroxybenzoate Solution | APF | 0.06 | 0.59 | 5.86 | 58.57 |
| Methylated Industrial Spirit (use as additive only) | BP | 0.01 | 0.02 | 0.15 | 1.31 |
| Olive Oil (use as additive only) | BP | 0.03 | 0.26 | 2.37 | 21.11 |
| Paraffin Hard | BP | 0.09 | 0.92 | 8.30 | 73.77 |
| Paraffin Light Liquid | BP | 0.02 | 0.16 | 1.40 | 8.91 |
| Paraffin Liquid (use as additive only) | BP | 0.01 | 0.12 | 1.08 | 9.61 |
| Paraffin Soft White | BP | 0.01 | 0.15 | 1.31 | 11.68 |
| Peppermint Oil (use as additive only) | BP | 0.25 | 2.54 | 22.82 | 144.89 |

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL $ | 1 g/mL $ | 10 g/mL $ | 100 g/mL $ |
| Peppermint Water Concentrated 1 in 40 (use as additive only) | APF 16 | 0.05 | 0.46 | 4.10 | 36.48 |
| Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy) | BP | 1.71 | 17.15 | 154.34 | 979.92 |
| Phenol Liquefied (not available for ear drops) | BP | 0.58 | 5.77 | 51.91 | 329.58 |
| Podophyllum Resin | BP | 11.44 | 114.42 | 653.85 | 6538.50 |
| Potassium Citrate | BP | 0.04 | 0.41 | 3.71 | 33.00 |
| Potassium Iodide | BP | 0.16 | 1.59 | 14.32 | 90.92 |
| Potassium Permanganate | BP | 0.06 | 0.57 | 5.15 | 45.74 |
| Propyl Hydroxybenzoate | BP | 0.30 | 2.98 | 26.79 | 170.08 |
| Propylene Glycol | BP | 0.04 | 0.42 | 3.79 | 24.05 |
| Resorcinol | BP | 0.45 | 3.57 | 28.59 | 254.15 |
| Salicylic Acid | BP | 0.07 | 0.67 | 6.03 | 38.31 |
| Salicylic Acid Ointment | APF | 0.02 | 0.17 | 1.38 | 12.23 |
| Salicylic Acid Ointment | BP | 0.02 | 0.17 | 1.38 | 12.23 |
| Simple Ointment (white) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.20 | 1.82 | 16.15 |
| Simple Ointment (yellow) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.14 | 1.11 | 9.88 |
| Sodium Bicarbonate | BP | 0.02 | 0.23 | 2.06 | 18.35 |
| Sodium Chloride | BP | 0.03 | 0.34 | 3.06 | 27.23 |
| Sodium Chloride Solution | BP | 0.01 | 0.02 | 0.15 | 1.50 |
| Sodium Citrate | BP | 0.06 | 0.59 | 5.31 | 33.71 |
| Sodium Thiosulfate (use as additive only) | BP | 0.12 | 1.16 | 10.46 | 92.99 |
| Starch | BP | 0.02 | 0.21 | 1.88 | 16.67 |
| Sulfur Ointment (for use only as a base combined with active ingredients) | BP 1980 | 0.02 | 0.24 | 2.42 | 24.19 |
| Sulfur Precipitated | BP 1980 | 0.11 | 1.06 | 9.55 | 60.60 |
| Syrup | BP | 0.01 | 0.12 | 1.09 | 9.68 |
| Talc Purified, sterilised | BP | 0.08 | 0.80 | 7.18 | 63.80 |
| Thymol | BP | 0.34 | 3.44 | 30.95 | 196.48 |
| Thymol Compound Mouth Wash | APF 15 | 0.01 | 0.11 | 0.96 | 8.54 |
| Tragacanth Compound Powder | BP 1980 | 0.07 | 0.57 | 4.58 | 40.73 |
| Tragacanth Mucilage | APF 13 | 0.01 | 0.14 | 1.38 | 13.77 |
| Tragacanth Mucilage | BPC 1973 | 0.01 | 0.13 | 1.30 | 13.03 |
| Tragacanth, powdered | BP | 0.93 | 9.30 | 83.70 | 531.42 |
| Trichloroacetic Acid | BP 1980 | 0.62 | 6.21 | 55.89 | 354.88 |
| Triethanolamine | BP | 0.20 | 2.01 | 18.05 | 114.62 |
| Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions) | BP | 0.00 | 0.00 | 8.81 | 8.81 |
| Water Purified | BP | 0.01 | 0.02 | 0.14 | 1.21 |
| Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients) | BP | 0.03 | 0.21 | 1.64 | 14.55 |
| Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients) | BP | 0.02 | 0.19 | 1.48 | 13.18 |
| Wool Fat | BP | 0.04 | 0.42 | 3.75 | 33.31 |

| Drug | Standard | Recovery Prices | | | |
|---|---|---|---|---|---|
| | | 0.1 g/mL $ | 1 g/mL $ | 10 g/mL $ | 100 g/mL $ |
| Wool Fat Hydrous | BP | 0.03 | 0.30 | 2.70 | 24.02 |
| Zinc Compound Paste | BP | 0.06 | 0.58 | 5.18 | 46.07 |
| Zinc Cream (for use only as a base combined with active ingredients) | BP | 0.02 | 0.19 | 1.67 | 14.84 |
| Zinc Oxide | BP | 0.04 | 0.38 | 3.44 | 30.57 |
| Zinc and Salicylic Acid Paste | BP | 0.04 | 0.37 | 3.36 | 29.86 |
| Zinc Sulfate | BP | 0.07 | 0.68 | 6.16 | 39.14 |

# Container Prices

| Type | Container | Price $ |
|---|---|---|
| Dispensing Bottles | 25mL | 0.60 |
| Dispensing Bottles | 50mL | 0.75 |
| Dispensing Bottles | 100mL | 0.88 |
| Dispensing Bottles | 200mL | 0.96 |
| Dispensing Bottles | 500mL | 1.28 |
| Poison Bottles | 25mL | 1.21 |
| Poison Bottles | 50mL | 1.34 |
| Poison Bottles | 100mL | 1.34 |
| Poison Bottles | 200mL | 1.48 |
| Poison Bottles | 500mL | 2.00 |
| Poison Bottles | 600mL | 4.05 |
| Poison Bottles | 1000mL | 3.99 |
| Dropper Containers (Glass) | 15mL | 1.42 |
| Dropper Containers (Polythene) | 15mL | 0.98 |
| Screw Cap Jars | 25g | 1.10 |
| Screw Cap Jars | 50g | 1.37 |
| Screw Cap Jars | 100g | 1.43 |
| Screw Cap Jars | 200g | 0.77 |
| Screw Cap Jars | 500g | 2.19 |
| Screw Cap Jars | 1000g | 4.39 |

# Standard Formula Preparations

| Code | Item | Reference | DPMQ $ | MRVSN $ |
|---|---|---|---|---|
| | **Creams (Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7502W | Salicylic Acid and Sulfur Aqueous | APF | 21.18 | 23.17 |
| | **Ear Drops (Maximum Quantity 15 ml and 2 Repeats)** | | | |
| 7642F | Aluminium Acetate | APF | 14.19 | 16.18 |
| 7643G | Aluminium Acetate | BP | 15.33 | 17.32 |
| 7314Y | Sodium Bicarbonate | APF & BP | 13.54 | 15.53 |
| 7313X | Spirit | APF | 12.80 | 14.79 |
| | **Inhalations (Maximum Quantity 50 ml and 1 Repeat)** | | | |
| 7484X | Benzoin and Menthol | APF | 43.22 | 25.00 |
| 7308P | Menthol | APF | 18.82 | 20.81 |
| 7310R | Menthol and Eucalyptus | BP1980 | 19.11 | 21.10 |
| | **Linctuses containing Codeine Phosphate (Maximum Quantity 100 ml and 0 Repeats)** | | | |
| 7530H | Codeine | APF | 23.45 | 25.00 |
| | **Lotions (Maximum Quantity 200 ml and 2 Repeats)** | | | |
| 7709R | Aluminium Acetate Aqueous | APF | 17.21 | 19.20 |
| | **Mixtures, Other (Maximum Quantity 200 ml and 4 Repeats)** | | | |
| 7348R | Kaolin | BPC 1968 | 56.58 | 25.00 |
| 7342K | Magnesium Trisilicate | BPC 1968 | 28.53 | 25.00 |
| 7343L | Magnesium Trisilicate and Belladonna | BPC 1968 | 48.17 | 25.00 |
| | **Ointments, Waxes (Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7914M | Benzoic Acid Compound | APF & BP | 33.53 | 25.00 |
| 7902X | Boric Acid, Olive Oil and Zinc Oxide | QHF | 25.84 | 25.00 |
| 7926E | Salicylic Acid | APF | 25.93 | 25.00 |
| 7928G | Salicylic Acid (extemporaneous formula) | BP | 25.93 | 25.00 |
| | **Paints (Maximum Quantity 25 ml and 1 Repeat)** | | | |
| 7567G | Podophyllin Compound | APF 16 & BP | 453.40 | 25.00 |
| 7568H | Salicylic Acid | APF | 152.66 | 25.00 |
| | **Pastes, Other (Maximum Quantity 100 g and 1 Repeat)** | | | |
| 7558T | Zinc | APF & BP | 58.74 | 25.00 |
| | **Powders for Internal Use (Maximum Quantity 100 g and 2 Repeats)** | | | |
| 7545D | Magnesium Trisilicate | BP | 61.31 | 25.00 |

# Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

| Code | Preparation | Maximum Quantity | Number of Repeats |
|---|---|---|---|
| 13Q | Creams | 100 g | 1 |
| 48M | Dusting Powders | 100 g | 1 |
| 15T | Ear Drops | 15 ml | 2 |
| 19B | Eye Drops containing Cocaine Hydrochloride | 15 ml | 0 |
| 22E | Eye Drops, Other | 15 ml | 5 |
| 23F | Eye Lotions | 200 ml | 2 |
| 29M | Inhalations | 50 ml | 1 |
| 64J | Linctuses containing Codeine Phosphate | 100 ml | 0 |
| 34T | Linctuses, Other | 100 ml | 2 |
| 39C | Lotions | 200 ml | 2 |
| 65K | Mixtures containing Codeine Phosphate | 200 ml | 0 |
| 66L | Mixtures for Children containing Codeine Phosphate | 100 ml | 0 |
| 41E | Mixtures for Children, Other | 100 ml | 4 |
| 40D | Mixtures, Other | 200 ml | 4 |
| 30N | Mouth Washes | 200 ml | 1 |
| 42F | Nasal Instillations | 15 ml | 2 |
| 43G | Ointments, Waxes | 100 g | 1 |
| 44H | Paints | 25 ml | 1 |
| 63H | Pastes containing Cocaine Hydrochloride | 25 g | 0 |
| 45J | Pastes, Other | 100 g | 1 |
| 49N | Powders for Internal Use | 100 g | 2 |
| 52R | Solutions | 200 ml | 2 |

# Index of Manufacturer Codes

| Code | Manufacturer |
|---|---|
| **AB** | Abbott Australasia Pty Ltd |
| **AE** | AFT Pharmaceuticals (AU) Pty Ltd |
| **AF** | Alphapharm Pty Ltd |
| **AL** | Alphapharm Pty Ltd |
| **AN** | Amgen Australia Pty Limited |
| **AP** | AstraZeneca Pty Ltd |
| **AQ** | Alcon Laboratories (Australia) Pty Ltd |
| **AS** | Aspen Pharmacare Australia Pty Limited |
| **AV** | sanofi-aventis Australia Pty Ltd |
| **BB** | Blackmores Limited |
| **BD** | Biogen Australia Pty Ltd |
| **BG** | Sandoz Pty Ltd |
| **BN** | Bayer Australia Ltd |
| **BQ** | Bristol-Myers Squibb Australia Pty Ltd |
| **BX** | BAXTER HEALTHCARE PTY LTD |
| **BY** | Boehringer Ingelheim Pty Ltd |
| **BZ** | Boucher & Muir Pty Ltd |
| **CR** | Pharmacor Pty Limited |
| **CS** | Seqirus (Australia) Pty Ltd |
| **CX** | Contact Lens Centre Australia Limited |
| **DE** | Stallergenes Australia Pty Ltd |
| **DX** | Ascensia Diabetes Care Australia Pty Limited |
| **DZ** | Medsurge Healthcare Pty Ltd |
| **EI** | Eisai Australia Pty Ltd |
| **EO** | Ego Pharmaceuticals Pty Ltd |
| **EU** | Chiesi Australia Pty Ltd |
| **EV** | Teva Pharma Australia Pty Ltd |
| **EW** | Celltrion Healthcare Australia Pty Ltd |
| **FB** | Pierre Fabre Australia Pty Ltd |
| **FD** | Dr Falk Pharma Australia Pty Ltd |
| **FF** | Phebra Pty Ltd |
| **FG** | Phebra Pty Ltd |
| **FJ** | Pharmaco (Australia) Limited |
| **FK** | A.Menarini Australia Pty Limited |
| **FP** | Ferring Pharmaceuticals Pty Limited |
| **FQ** | Pharmaco (Australia) Limited |
| **FT** | AMICUS THERAPEUTICS PTY LTD |
| **FW** | NEURAXPHARM AUSTRALIA PTY LIMITED |
| **FX** | Gedeon Richter Australia Pty Ltd |
| **FY** | Pharmacor Pty Limited |
| **FZ** | Pfizer Australia Pty Ltd |
| **GA** | Galderma Australia Pty Ltd |
| **GC** | GlaxoSmithKline Australia Pty Ltd |
| **GH** | Amdipharm Mercury (Australia) Pty Limited |
| **GI** | Gilead Sciences Pty Limited |
| **GK** | GlaxoSmithKline Australia Pty Ltd |
| **GO** | Viatris Pty Ltd |
| **GQ** | Generic Health Pty Ltd |
| **GT** | Viatris Pty Ltd |
| **GX** | Apotex Pty Ltd |
| **GZ** | sanofi-aventis Australia Pty Ltd |
| **HB** | Besins Healthcare Australia Pty Ltd |
| **HJ** | Maple Healthcare Pty Ltd |
| **HK** | SEED PHARMA PTY. LTD. |
| **HQ** | Generic Health Pty Ltd |
| **HW** | HAMELN PHARMA PTY. LTD. |
| **HX** | Sandoz Pty Ltd |
| **IE** | BEONE MEDICINES AUS PTY LTD |
| **IL** | iNova Pharmaceuticals (Australia) Pty Limited |
| **IM** | iNova Pharmaceuticals (Australia) Pty Limited |
| **IO** | BioMarin Pharmaceutical Australia Pty Ltd |
| **IQ** | Alcon Laboratories (Australia) Pty Ltd |
| **IS** | Ipsen Pty Ltd |
| **IT** | InterPharma Pty Ltd |
| **IU** | AUPHARMA PTY LTD |
| **IX** | Clinect Pty Ltd |
| **IY** | Clinect Pty Ltd |
| **JA** | JAZZ PHARMACEUTICALS ANZ PTY LTD |
| **JC** | Janssen-Cilag Pty Ltd |
| **JG** | Merck Healthcare Pty Ltd |
| **JM** | Glenmark Pharmaceuticals (Australia) Pty Ltd |
| **JO** | Juno Pharmaceuticals Pty Ltd |
| **JT** | Johnson & Johnson Pacific Pty Limited |
| **JU** | Juno Pharmaceuticals Pty Ltd |
| **JW** | Asteri Pharma Pty Ltd |
| **JX** | Juno Pharmaceuticals Pty Ltd |
| **KF** | BIOCELECT PTY LTD |
| **KP** | Eli Lilly Australia Pty Ltd |
| **KQ** | PHERO PHARMA PTY LTD |
| **KT** | ACTOR PHARMACEUTICALS PTY LTD |
| **KY** | Key Pharmaceuticals Pty Ltd |
| **LD** | Lacuna Pharma Pty Ltd |
| **LJ** | Anthia Life Sciences Pty Ltd |
| **LL** | Astellas Pharma Australia Pty Ltd |
| **LM** | Link Medical Products Pty Ltd |
| **LN** | Aspen Pharmacare Australia Pty Limited |
| **LO** | Leo Pharma Pty Ltd |
| **LQ** | Astellas Pharma Australia Pty Ltd |
| **LR** | Cipla Australia Pty Ltd |
| **LT** | Aspen Pharmacare Australia Pty Limited |
| **LU** | Lundbeck Australia Pty Ltd |
| **LX** | Lawley Pharmaceuticals Pty Ltd |
| **LY** | Eli Lilly Australia Pty Ltd |
| **MF** | Mundipharma Pty Limited |
| **MK** | Merck Sharp & Dohme (Australia) Pty Ltd |
| **MQ** | Alphapharm Pty Ltd |
| **NB** | Nova Pharmaceuticals Australasia Pty Ltd |
| **NE** | Norgine Pty. Ltd. |
| **NF** | Novo Nordisk Pharmaceuticals Pty. Limited |
| **NG** | NEON HEALTHCARE PTY LIMITED |
| **NM** | Novartis Pharmaceuticals Australia Pty Limited |
| **NO** | Novo Nordisk Pharmaceuticals Pty. Limited |
| **NP** | NICE-PAK PRODUCTS PTY. LTD. |
| **NQ** | Takeda Pharmaceuticals Australia Pty. Ltd. |

| Code | Manufacturer |
|---|---|
| **NT** | Nestle Australia Ltd |
| **NU** | Nutricia Australia Pty Limited |
| **NV** | Novartis Pharmaceuticals Australia Pty Limited |
| **OC** | Accord Healthcare Pty. Ltd. |
| **OH** | Orpharma Pty Ltd |
| **OJ** | The Trustee for ORSPEC PHARMA UNIT TRUST |
| **ON** | Orion Laboratories Pty. Ltd. |
| **OQ** | Organon Pharma Pty Ltd |
| **OS** | Otsuka Australia Pharmaceutical Pty. Ltd |
| **OW** | Arrow Pharma Pty Ltd |
| **OX** | Orion Pharma (Aus) Pty Limited |
| **PB** | Pharmaco (Australia) Limited |
| **PF** | Pfizer Australia Pty Ltd |
| **PK** | Fresenius Kabi Australia Pty Limited |
| **PP** | Petrus Pharmaceuticals Pty Ltd |
| **QH** | Cortex Health Pty Ltd |
| **QS** | Sandoz Pty Ltd |
| **QY** | Pro Pharmaceuticals Group Pty. Ltd. |
| **RA** | Sun Pharma ANZ Pty Ltd |
| **RF** | Arrow Pharma Pty Ltd |
| **RI** | Dr Reddy's Laboratories (Australia) Pty Ltd |
| **RJ** | Recordati Rare Diseases Australia Pty. Ltd. |
| **RN** | Sun Pharma ANZ Pty Ltd |
| **RO** | Roche Products Pty Ltd |
| **RQ** | Reach Pharmaceuticals Pty Ltd |
| **RW** | Arrow Pharma Pty Ltd |
| **RX** | Servier Laboratories (Aust.) Pty. Ltd. |
| **RZ** | Dr Reddy's Laboratories (Australia) Pty Ltd |
| **SB** | Nutricia Australia Pty Limited |
| **SE** | Servier Laboratories (Aust.) Pty. Ltd. |
| **SG** | Merck Healthcare Pty Ltd |
| **SI** | Sigma Company Limited |
| **SW** | sanofi-aventis Australia Pty Ltd |
| **SY** | Bayer Australia Ltd |
| **SZ** | Sandoz Pty Ltd |
| **TB** | Teva Pharma Australia Pty Ltd |
| **TD** | STADA Pharmaceuticals Australia Pty Limited |
| **TJ** | Taiho Pharma Oceania Pty Ltd |
| **TK** | Takeda Pharmaceuticals Australia Pty. Ltd. |
| **TN** | Medtas Pty Ltd |
| **TT** | Theramex Australia Pty Ltd |
| **TW** | Apotex Pty Ltd |
| **TX** | Apotex Pty Ltd |
| **TY** | Apotex Pty Ltd |
| **UC** | UCB Australia Proprietary Limited |
| **UI** | PERRIGO AUSTRALIA PTY LIMITED |
| **UL** | Bausch & Lomb (Australia) Pty Ltd |
| **UO** | Bausch & Lomb (Australia) Pty Ltd |
| **VB** | AbbVie Pty Ltd |
| **VE** | AbbVie Pty Ltd |
| **VF** | Vitaflo Australia Pty Limited |
| **VJ** | VITALION PTY LTD |
| **VK** | CSL BEHRING (AUSTRALIA) PTY LTD |
| **VM** | MSN LABORATORIES AUSTRALIA PTY LTD |
| **VQ** | Novartis Pharmaceuticals Australia Pty Limited |
| **VY** | Alphapharm Pty Ltd |
| **VZ** | Sanofi-aventis Healthcare Pty Ltd |
| **WA** | sanofi-aventis Australia Pty Ltd |
| **WG** | WAGNER PHARMACEUTICALS PTY LTD |
| **WM** | MEDISON PHARMA AUSTRALIA PTY LIMITED |
| **WZ** | Bridgewest Perth Pharma Pty Ltd |
| **XC** | Southern Cross Pharma Pty Ltd |
| **XG** | ALGORAERX PTY LTD |
| **XH** | MS Health Pty Ltd |
| **XI** | Alexion Pharmaceuticals Australasia Pty Ltd |
| **XN** | Southern XP Pty Ltd |
| **XO** | Echo Therapeutics Pty Ltd |
| **XT** | Arrotex Pharmaceuticals Pty Ltd |
| **XW** | Arrotex Pharmaceuticals Pty Ltd |
| **XY** | MAXX PHARMA PTY LTD |
| **YN** | Mayne Pharma International Pty Ltd |
| **YO** | The Trustee for ORSPEC PHARMA UNIT TRUST |
| **YT** | Mayne Products Pty Ltd |
| **ZB** | Specialised Therapeutics Pm Pty Ltd |
| **ZE** | Seekwell Pty Ltd |
| **ZS** | Strides Pharma Science Pty Ltd |

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10048W (SAXAGLIPTIN + METFORMIN).....100
1004W (ACETAZOLAMIDE).....1710
10051B (SAXAGLIPTIN + METFORMIN).....101
10052C (PAZOPANIB).....470
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10055F (SAXAGLIPTIN + METFORMIN).....101
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10061M (DENOSUMAB).....1490
10062N (TEMOZOLOMIDE).....357
10066T (TOBRAMYCIN).....329
10074F (TOBRAMYCIN).....329
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10080M (CLOBETASOL).....250
10086W (SAPROPTERIN).....130
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10128C (SAXAGLIPTIN).....109
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10137M (CERTOLIZUMAB PEGOL).....859
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10157N (PERAMPANEL).....1565
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10174L (ENZALUTAMIDE).....526
10176N (DOXYCYCLINE).....307
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10250L (SUCROFERRIC OXYHYDROXIDE) .....1750
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10258X (AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE) .....1782
10259Y (AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE).....1784
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10293R (LACOSAMIDE).....1556
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10330Q (ESOMEPRAZOLE) .....23
10331R (ESOMEPRAZOLE) .....22
10332T (GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS) .1787
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1034K (TERBUTALINE).....1700
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10376D (EZETIMIBE + ATORVASTATIN) .....235
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10378F (TESTOSTERONE) .....268
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10399H (ADALIMUMAB) .....684
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10517M (TOFACITINIB) .....1384
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10529E (LURASIDONE).....1590
1052J (ACICLOVIR).....344
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10757E (OXYCODONE + NALOXONE).....1523
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10776E (OXYCODONE + NALOXONE).....1522
10777F (DOXYCYCLINE).....307
10778G (CEFALEXIN).....320
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10780J (ERYTHROMYCIN).....326
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10897M (CERTOLIZUMAB PEGOL).....847
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1089H (ATROPINE SULFATE).....49
10900Q (SECUKINUMAB).....1194
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10904X (CERTOLIZUMAB PEGOL).....865
10905Y (CERTOLIZUMAB PEGOL).....870
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10955N (ADALIMUMAB) ..... 629
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11032P (IXEKIZUMAB) ..... 1130
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11076Y (VEMURAFENIB) ..... 407
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11095Y (SALBUTAMOL) ..... 1657
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11262R (EVEROLIMUS) ..... 427
11263T (ERLOTINIB) ..... 400
11264W (GEFITINIB) ..... 401
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11267B (EVEROLIMUS) ..... 426
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11275K (METHOTREXATE) ..... 1468
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11302W (INSULIN GLARGINE).....89
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11317P (DEXAMETHASONE).....1704
11318Q (CERTOLIZUMAB PEGOL) .....847
11319R (CERTOLIZUMAB PEGOL).....865
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11320T (CERTOLIZUMAB PEGOL).....859
11321W (CERTOLIZUMAB PEGOL).....846
11322X (CERTOLIZUMAB PEGOL).....870
11323Y (CERTOLIZUMAB PEGOL).....877
11324B (CERTOLIZUMAB PEGOL).....861
11325C (CERTOLIZUMAB PEGOL).....857
11326D (CERTOLIZUMAB PEGOL).....849
11327E (BRIVARACETAM).....1552
11328F (BRIVARACETAM).....1553
11331J (AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS) .....1775
11334M (BRIVARACETAM) .....1553
11335N (AFATINIB).....399
11336P (AFATINIB) .....398
11338R (BRIVARACETAM).....1552
11339T (BRIVARACETAM) .....1553
11340W (AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS) .....1777
11341X (AFATINIB) .....399
11343B (AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS) .....1774
11344C (GLECAPREVIR + PIBRENTASVIR).....352
11347F (AFATINIB) .....398
11348G (AFATINIB).....398
11349H (BRIVARACETAM).....1553
11350J (BRIVARACETAM).....1552
11351K (BALSALAZIDE) .....79
11353M (GLECAPREVIR + PIBRENTASVIR).....353
11354N (GLECAPREVIR + PIBRENTASVIR).....353
11356Q (BRIVARACETAM).....1553
11357R (BRIVARACETAM).....1552
11358T (BRIVARACETAM) .....1553
11359W (AFATINIB) .....399
11360X (CABOZANTINIB).....454
11361Y (GOLIMUMAB) .....1034
11362B (EVEROLIMUS).....429
11364D (DULAGLUTIDE).....113
11365E (GOLIMUMAB) .....1030
11366F (LINCOMYCIN).....328
11367G (CABOZANTINIB) .....454
11368H (CABOZANTINIB).....454
11369J (CABOZANTINIB) .....454
11371L (CABOZANTINIB) .....454
11372M (GOLIMUMAB).....1025
11373N (GOLIMUMAB) .....1011
11374P (CABOZANTINIB).....454
11375Q (GOLIMUMAB) .....1009
11376R (GOLIMUMAB) .....1013
11377T (EVEROLIMUS).....429
11379X (FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL).....1683
11380Y (LINCOMYCIN).....328
11381B (GOLIMUMAB) .....1015
11382C (GOLIMUMAB) .....1020
11385F (RIBOCICLIB) .....424
11386G (RIBOCICLIB).....425
11397W (RIBOCICLIB).....426
11406H (PIRFENIDONE).....1471
11407J (PERAMPANEL) .....1566
11409L (PERAMPANEL) .....1566
11410M (PIRFENIDONE) .....1469
11416W (PEGINTERFERON ALFA-2A).....533
11418Y (PERAMPANEL).....1566
11419B (IBRUTINIB).....447
11426J (INSULIN DEGLUDEC + INSULIN ASPART).....88
11428L (PERAMPANEL) .....1566
11429M (PERAMPANEL) .....1566
11436X (PERAMPANEL).....1566
11437Y (BARICITINIB) .....1365
11439C (PERFLUOROHEXYLOCTANE).....1744
11440D (GUANFACINE).....1630
11441E (GUANFACINE).....1630
11442F (BARICITINIB) .....1360
11443G (BARICITINIB).....1360
11446K (PERFLUOROHEXYLOCTANE) .....1744
11447L (BARICITINIB).....1365
11451Q (GUANFACINE) .....1629
11452R (GUANFACINE).....1629
11453T (PONATINIB) .....396
11454W (PONATINIB).....396
11469P (DEXAMETHASONE).....1707
11471R (RANIBIZUMAB).....1736
11480F (RANIBIZUMAB).....1736
11484K (EVOLOCUMAB) .....228
11502J (GOLIMUMAB).....1004
11503K (OLAPARIB) .....502
11507P (TRIFLURIDINE + TIPIRACIL) .....363
11516D (GOLIMUMAB) .....1016
11521J (GOLIMUMAB).....1017
11522K (OLAPARIB) .....503
11524M (TRIFLURIDINE + TIPIRACIL).....363
11528R (OLAPARIB) .....503
11538G (GOLIMUMAB).....1037
11539H (OLAPARIB) .....502
1153Q (CARBIMAZOLE) .....301
11554D (MESALAZINE) .....81
11559J (CLONAZEPAM) .....1547
11560K (GOLIMUMAB) .....1038
11565Q (TOCILIZUMAB).....1269
11567T (TOCILIZUMAB) .....1245
11588X (TOLVAPTAN).....179
11589Y (CRIZOTINIB).....412
11591C (EVEROLIMUS).....427
11592D (EVEROLIMUS).....427
11593E (TOLVAPTAN).....179
11594F (CRIZOTINIB) .....412
11596H (TOLVAPTAN).....179
11597J (TOLVAPTAN).....179
11598K (EVEROLIMUS).....428
11599L (EVEROLIMUS) .....427
11600M (TOLVAPTAN) .....179
11602P (TOLVAPTAN).....179
11603Q (CLADRIBINE) .....547
11604R (CLADRIBINE).....547
11607X (EVEROLIMUS).....427
11608Y (EVEROLIMUS).....427
11611D (CLADRIBINE).....547
11613F (TILDRAKIZUMAB).....1218
11614G (GUSELKUMAB).....1117
11615H (FERRIC DERISOMALTOSE).....152
11616J (TILDRAKIZUMAB) .....1208
11621P (ISOTRETINOIN).....252

11623R (IXEKIZUMAB) ....1123
11625W (HYPROMELLOSE)....1742
11629C (TIOTROPIUM)....1694
11630D (VENETOCLAX)....514
11633G (RIVAROXABAN)....146
11634H (HYPROMELLOSE) ....1742
11638M (LENVATINIB)....463
11639N (VENETOCLAX)....511
1163F (CHLORAMBUCIL)....355
11640P (GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS) .1787
11645X (INSULIN LISPRO)....87
11648C (VENETOCLAX)....512
11656L (SAFINAMIDE)....1586
11658N (SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR)....353
1165H (DEXAMFETAMINE) ....1632
11662T (RILUZOLE)....1650
11666B (SAFINAMIDE) ....1586
11669E (LANSOPRAZOLE) ....31
1166J (PHENOXYBENZAMINE) ....180, 282
11670F (RABEPRAZOLE)....46
11675L (TOFACITINIB) ....1376
11676M (SAPROPTERIN)....132
11677N (OMEPRAZOLE) ....36
11678P (PANTOPRAZOLE) ....42
11681T (PANTOPRAZOLE) ....42
11682W (OMEPRAZOLE) ....36
11683X (OMEPRAZOLE) ....36
11684Y (ABATACEPT)....540
11687D (ESOMEPRAZOLE) ....24
11690G (TOFACITINIB)....1389
11691H (SAPROPTERIN) ....133
11692J (ESOMEPRAZOLE) ....24
11693K (ABATACEPT)....545
11694L (LACOSAMIDE) ....1559
11697P (LANSOPRAZOLE) ....31
1169M (CEFACLOR) ....322
11702X (FERRIC CARBOXYMALTOSE) ....152
11703Y (ETHOSUXIMIDE)....1546
11716P (ISOTRETINOIN)....251
11719T (FLUTICASONE FUROATE) ....1690
11720W (TOCILIZUMAB) ....1226
11721X (TOCILIZUMAB) ....1239
11722Y (TOCILIZUMAB) ....1239
11723B (BENZATHINE BENZYLPENICILLIN)....312
11725D (TOCILIZUMAB)....1257
11726E (CALCIUM) ....124
11729H (FLUTICASONE FUROATE)....1690
11730J (TOCILIZUMAB)....1237
11734N (TOCILIZUMAB)....1260
11735P (BENZATHINE BENZYLPENICILLIN)....312
11740X (TESTOSTERONE)....265
11741Y (TOCILIZUMAB)....1257
11742B (TOCILIZUMAB)....1226
11743C (TOCILIZUMAB)....1252
11744D (TOCILIZUMAB)....1252
11748H (TOCILIZUMAB)....1260
11750K (TOCILIZUMAB)....1237
11752M (IMATINIB) ....389
11753N (IMATINIB)....377
11756R (IMATINIB)....377
11757T (IMATINIB)....378
11758W (IMATINIB)....378
11762C (IMATINIB)....379
11763D (IMATINIB)....378
11764E (IMATINIB)....379
11765F (IMATINIB)....377
11769K (IMATINIB)....378
11770L (IMATINIB) ....380
11771M (IMATINIB) ....384
11772N (IMATINIB)....389
11775R (IMATINIB)....390
11776T (IMATINIB)....377
11777W (IMATINIB)....379
11778X (IMATINIB)....385
11779Y (IMATINIB)....380
11780B (IMATINIB)....386
11781C (IMATINIB)....380
11782D (IMATINIB)....390
11783E (IMATINIB)....386
11784F (IMATINIB)....381
11785G (IMATINIB) ....380
11786H (IMATINIB)....379
11787J (IMATINIB) ....386
11788K (IMATINIB)....381
11789L (IMATINIB) ....384
1180D (AMINO ACID SYNTHETIC FORMULA)....1756
11815W (INSULIN GLARGINE)....88
11816X (NALOXONE) ....1748
11817Y (NALOXONE) ....1748
11818B (FINGOLIMOD)....1349
11819C (TRAMETINIB) ....418
11820D (DABRAFENIB) ....403
11821E (TRAMETINIB)....418
11822F (MUPIROCIN)....1655
11823G (DABRAFENIB)....403
1182F (FOSINOPRIL)....191
11832R (GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACID FORMULA WITH VITAMINS, MINERALS, AND LOW IN TYROSINE AND PHENYLALANINE) .1787
11836Y (AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID)....1784
1183G (FOSINOPRIL) ....191
11842G (HYPROMELLOSE) ....1743
11844J (GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE)....1789
11849P (HYPROMELLOSE)....1743
11852T (CARMELLOSE SODIUM)....1739
11853W (CARMELLOSE SODIUM) ....1739
11856B (SEVELAMER) ....1750
11859E (AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID)....1784
11865L (SODIUM PHENYLBUTYRATE)....134
11868P (ABEMACICLIB) ....420
11869Q (RISPERIDONE) ....1602
11871T (ABEMACICLIB) ....420
11874Y (RISPERIDONE)....1602
11876C (ABEMACICLIB)....420
11877D (RISPERIDONE) ....1602
11879F (RISPERIDONE)....1603
11881H (RISPERIDONE) ....1603
11882J (RISPERIDONE) ....1603
11884L (LISDEXAMFETAMINE) ....1633
11892X (TIOTROPIUM)....1696
11897E (LISDEXAMFETAMINE)....1633
11898F (LISDEXAMFETAMINE) ....1633
11908R (PREDNISOLONE ACETATE + PHENYLEPHRINE)....1708
11909T (LEVONORGESTREL) ....259
11914C (TACROLIMUS)....1342
11919H (LEVODOPA + CARBIDOPA) ....1576
11921K (ISOTRETINOIN)....251

1192R (AMINO ACID SYNTHETIC FORMULA).....1757
11933C (AMOXICILLIN + CLAVULANIC ACID).....316
11934D (CEFALEXIN).....320
11937G (ENCORAFENIB).....406
11938H (ENCORAFENIB).....406
11939J (PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS AND MINERALS).....1754
11941L (AMOXICILLIN + CLAVULANIC ACID).....317
11943N (LEUPRORELIN).....519
11944P (LEUPRORELIN).....519
11947T (AMOXICILLIN).....311
11948W (BINIMETINIB).....413
11949X (ENCORAFENIB).....407
11954E (ENCORAFENIB).....407
1195X (CHLORPROMAZINE).....1589
11960L (LEUPRORELIN).....519
11961M (BINIMETINIB).....413
11963P (CEFALEXIN).....321
11970B (SAPROPTERIN).....131
11971C (SAPROPTERIN).....132
11973E (SAPROPTERIN).....131
11974F (BRIGATINIB).....409
11975G (RANIBIZUMAB).....1737
11976H (BRIGATINIB).....410
11977J (EVOLOCUMAB).....225
11979L (UPADACITINIB).....1412
1197B (CHLORPROMAZINE).....1589
11980M (BRIGATINIB).....409
11981N (RANIBIZUMAB).....1737
11983Q (SAPROPTERIN).....133
11984R (BRIGATINIB).....409
11985T (EVOLOCUMAB).....229
11989B (UPADACITINIB).....1430
11991D (AFLIBERCEPT).....1727
11993F (ROXITHROMYCIN).....327
11998L (AMOXICILLIN).....311
1199D (CHLORPROMAZINE).....1589
12001P (ROXITHROMYCIN).....327
12002Q (AMOXICILLIN).....311
12005W (CERTOLIZUMAB PEGOL).....853
12006X (AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT METHIONINE).....1777
12008B (TRAMADOL).....1533
12009C (MORPHINE).....1506
12010D (HYDROMORPHONE).....1500
12013G (CERTOLIZUMAB PEGOL).....851
12014H (AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT VALINE, LEUCINE AND ISOLEUCINE).....1777
12015J (AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE AND TYROSINE).....1777
12016K (HYDROMORPHONE).....1500
1201F (CHLORPROMAZINE).....1589
12022R (PARACETAMOL + CODEINE).....1529
12024W (TRAMADOL).....1533
12027B (CERTOLIZUMAB PEGOL).....873
12028C (CERTOLIZUMAB PEGOL).....853
12029D (BUDESONIDE + FORMOTEROL).....1665
12031F (OXYCODONE).....1516
12032G (HYDROMORPHONE).....1500
12033H (TRIFLURIDINE + TIPIRACIL).....364
12040Q (CERTOLIZUMAB PEGOL).....851
12041R (BUDESONIDE + FORMOTEROL).....1666
12042T (BUDESONIDE + FORMOTEROL).....1661
12045Y (HYDROMORPHONE).....1500
12046B (HYDROMORPHONE).....1500
12047C (HYDROMORPHONE).....1500
12049E (FERRIC DERISOMALTOSE).....152
12054K (CODEINE).....1498
12055L (MORPHINE).....1514
12056M (TRIFLURIDINE + TIPIRACIL).....363
12063X (CERTOLIZUMAB PEGOL).....873
12065B (CODEINE).....1498
12066C (PARACETAMOL + CODEINE).....1529
12067D (MORPHINE).....1505
1206L (METOCLOPRAMIDE).....50
12072J (AMINO ACID FORMULA WITH CARBOHYDRATE WITHOUT PHENYLALANINE).....1777
12074L (OXYCODONE).....1516
12075M (SEMAGLUTIDE).....114
1207M (METOCLOPRAMIDE).....49
12082X (BUDESONIDE + FORMOTEROL).....1669
12083Y (TOCILIZUMAB).....1221
12084B (TOCILIZUMAB).....1247
12085C (TOCILIZUMAB).....1224
12086D (TOCILIZUMAB).....1248
12088F (STIRIPENTOL).....1567
12089G (BUDESONIDE + FORMOTEROL).....1669
1208N (CIPROFLOXACIN).....332
12090H (TOCILIZUMAB).....1248
12091J (LORLATINIB).....413
12092K (ENTRECTINIB).....457
12093L (BUDESONIDE + FORMOTEROL).....1669
12094M (TOCILIZUMAB).....1238
12095N (TOCILIZUMAB).....1221
12096P (LORLATINIB).....413
12099T (TOCILIZUMAB).....1247
1209P (CIPROFLOXACIN).....331
12101X (BUDESONIDE + FORMOTEROL).....1669
12102Y (TOCILIZUMAB).....1238
12103B (STIRIPENTOL).....1567
12105D (TOCILIZUMAB).....1224
12106E (STIRIPENTOL).....1567
12107F (STIRIPENTOL).....1567
12109H (SALBUTAMOL).....1657
1210Q (CIPROFLOXACIN).....331
12112L (CEFTRIAXONE).....324
12113M (IMIPRAMINE).....1610
12114N (CEFTRIAXONE).....324
12115P (CEFAZOLIN).....321
12116Q (METHYLPHENIDATE).....1637
12118T (CEFAZOLIN).....322
1211R (CLOMIFENE).....279
12131L (AFLIBERCEPT).....1723
12132M (AFLIBERCEPT).....1727
12133N (APOMORPHINE).....1580
12136R (AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE).....1782
12137T (APOMORPHINE).....1580
12141B (AFLIBERCEPT).....1723
12142C (APOMORPHINE).....1579
1214X (CODEINE).....1499
12152N (AFLIBERCEPT).....1724
12153P (AFLIBERCEPT).....1725
12157W (OLAPARIB).....504
12158X (SIPONIMOD).....1356
1215Y (PARACETAMOL + CODEINE).....1531
12161C (OLAPARIB).....502
12169L (OLAPARIB).....502
12170M (OLAPARIB).....504
12172P (SIPONIMOD).....1356
12175T (GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACID FORMULA WITH VITAMINS, MINERALS, AND LOW IN TYROSINE AND PHENYLALANINE).....1787
1217C (CIPROFLOXACIN).....1704
12183F (BECLOMETASONE + FORMOTEROL).....1659
12188L (VENETOCLAX).....515
12189M (RIFAMPICIN).....341
12190N (RIFAMPICIN).....341

12191P (PROTEIN FORMULA WITH VITAMINS AND MINERALS, AND LOW IN POTASSIUM, PHOSPHORUS, CALCIUM, CHLORIDE AND VITAMIN A) ..... 1791
12192Q (RIVAROXABAN) ..... 148
12197Y (RIVAROXABAN) ..... 147
12198B (MESALAZINE) ..... 83
12199C (VENETOCLAX) ..... 512
12200D (RIFAMPICIN) ..... 341
12203G (MESALAZINE) ..... 82
12205J (VENETOCLAX) ..... 512
12209N (IXEKIZUMAB) ..... 1132
1220F (ABATACEPT) ..... 545
12215X (RIFAMPICIN) ..... 342
12217B (IXEKIZUMAB) ..... 1139
12218C (APREMILAST) ..... 546
1221G (ABATACEPT) ..... 540
12223H (APREMILAST) ..... 546
12234X (INSULIN LISPRO + INSULIN LISPRO PROTAMINE) ..... 88
12236B (INSULIN DETEMIR) ..... 88
12237C (INSULIN LISPRO) ..... 87
12238D (INSULIN ASPART + INSULIN ASPART PROTAMINE) ..... 87
12254Y (INSULIN ASPART) ..... 86
12261H (INSULIN LISPRO + INSULIN LISPRO PROTAMINE) ..... 88
12267P (TERBUTALINE) ..... 1658
12268Q (INSULIN GLULISINE) ..... 87
12269R (INDACATEROL + MOMETASONE) ..... 1678
12270T (OMEPRAZOLE) ..... 38
12271W (OZANIMOD) ..... 1350
12272X (OMEPRAZOLE) ..... 38
12273Y (AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE) ..... 1780
12274B (AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE) ..... 1782
12275C (ESOMEPRAZOLE) ..... 26
12276D (LANSOPRAZOLE) ..... 32
12277E (PANTOPRAZOLE) ..... 43
12278F (OZANIMOD) ..... 1350
12279G (INDACATEROL + MOMETASONE) ..... 1678
12281J (OMEPRAZOLE) ..... 39
12282K (PANTOPRAZOLE) ..... 43
12283L (ESOMEPRAZOLE) ..... 28
12284M (LANSOPRAZOLE) ..... 32
12285N (AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE) ..... 1783
12286P (RABEPRAZOLE) ..... 47
12287Q (ESOMEPRAZOLE) ..... 26
12289T (INDACATEROL + MOMETASONE) ..... 1678
12290W (ESOMEPRAZOLE) ..... 28
12291X (DUPILUMAB) ..... 254
12292Y (DUPILUMAB) ..... 256
12295D (INDACATEROL + GLYCOPYRRONIUM + MOMETASONE) ..... 1686
12297F (SECUKINUMAB) ..... 1176
12298G (INDACATEROL + GLYCOPYRRONIUM + MOMETASONE) ..... 1686
12300J (FULVESTRANT) ..... 521
12301K (ROMOSOZUMAB) ..... 1492
12306Q (APOMORPHINE) ..... 1579
12307R (SECUKINUMAB) ..... 1173
12311Y (OXYCODONE) ..... 1516
12314D (OXYCODONE) ..... 1517
12319J (APOMORPHINE) ..... 1579
12321L (SECUKINUMAB) ..... 1186
12325Q (ADALIMUMAB) ..... 688
12326R (ADALIMUMAB) ..... 739
12327T (ADALIMUMAB) ..... 764
12328W (ADALIMUMAB) ..... 766
12329X (ADALIMUMAB) ..... 741
12330Y (ADALIMUMAB) ..... 689
12331B (ADALIMUMAB) ..... 590
12332C (ADALIMUMAB) ..... 632
12333D (ADALIMUMAB) ..... 623
12334E (ADALIMUMAB) ..... 691
12337H (ADALIMUMAB) ..... 802
12338J (ADALIMUMAB) ..... 599
12339K (ADALIMUMAB) ..... 832
1233X (TIOGUANINE) ..... 358
12340L (ADALIMUMAB) ..... 592
12342N (ADALIMUMAB) ..... 679
12345R (ADALIMUMAB) ..... 587
12347W (ADALIMUMAB) ..... 628
12350B (ADALIMUMAB) ..... 637
12351C (ADALIMUMAB) ..... 717
12352D (ADALIMUMAB) ..... 719
12353E (ADALIMUMAB) ..... 743
12354F (ADALIMUMAB) ..... 720
12356H (ADALIMUMAB) ..... 552
12357J (ADALIMUMAB) ..... 802
12358K (ADALIMUMAB) ..... 762
12359L (ADALIMUMAB) ..... 623
12360M (ADALIMUMAB) ..... 825
12361N (ADALIMUMAB) ..... 789
12362P (ADALIMUMAB) ..... 575
12363Q (ADALIMUMAB) ..... 795
12364R (ADALIMUMAB) ..... 818
12365T (ADALIMUMAB) ..... 693
12366W (ADALIMUMAB) ..... 732
12367X (ADALIMUMAB) ..... 744
12369B (ADALIMUMAB) ..... 768
12370C (ADALIMUMAB) ..... 629
12371D (ADALIMUMAB) ..... 637
12372E (ADALIMUMAB) ..... 813
12373F (ADALIMUMAB) ..... 595
12374G (ADALIMUMAB) ..... 832
12375H (ADALIMUMAB) ..... 792
12376J (ADALIMUMAB) ..... 579
12377K (ADALIMUMAB) ..... 845
12378L (ADALIMUMAB) ..... 566
12379M (ADALIMUMAB) ..... 684
12380N (ADALIMUMAB) ..... 589
12381P (ADALIMUMAB) ..... 592
12382Q (ADALIMUMAB) ..... 623
12383R (ADALIMUMAB) ..... 721
12385W (ADALIMUMAB) ..... 721
12386X (ADALIMUMAB) ..... 592
12387Y (ADALIMUMAB) ..... 583
12388B (ADALIMUMAB) ..... 596
12389C (ADALIMUMAB) ..... 715
12390D (ADALIMUMAB) ..... 756
12391E (ADALIMUMAB) ..... 759
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14284T (ADALIMUMAB).....771
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14466J (PANTOPRAZOLE)....41
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14469M (BUDESONIDE)....1690
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14797T (AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES).....1770
14799X (FARICIMAB).....1729
1479W (PRAZOSIN).....173
14808J (CLOBETASOL).....250
1480X (PRAZOSIN).....173
14812N (ESKETAMINE).....1624
14815R (ESKETAMINE).....1624
14817W (FARICIMAB).....1729
14818X (PRASUGREL).....139
14819Y (EPCORITAMAB).....492
14820B (GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS).....1788
14824F (ARIPIPRAZOLE).....1597
14825G (AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES).....1779
14830M (ESKETAMINE).....1625
14832P (CLOBETASOL).....250
14833Q (FENFLURAMINE).....1554
14836W (ESKETAMINE).....1625
14838Y (MESALAZINE).....84
14839B (TIOTROPIUM).....1695
14840C (MESALAZINE).....84
14841D (LIOTHYRONINE).....300
14842E (TIOTROPIUM).....1695
14843F (MESALAZINE).....85
14844G (SEMAGLUTIDE).....114
14845H (TIOTROPIUM).....1695
14846J (SEMAGLUTIDE).....114
14847K (MESALAZINE).....84
14848L (MESALAZINE).....84
14849M (TIOTROPIUM + OLODATEROL).....1687
1484D (HYDROCHLOROTHIAZIDE).....174
14850N (MESALAZINE).....85
14851P (RIBOCICLIB).....422
14852Q (ETANERCEPT).....935
14857Y (METHYLPHENIDATE).....1637
14862F (METHYLPHENIDATE).....1635
14863G (RIBOCICLIB).....423
14864H (FARICIMAB).....1732
14868M (IVOSIDENIB).....508
1486F (AMILORIDE + HYDROCHLOROTHIAZIDE).....178
14871Q (METHYLPHENIDATE).....1636
14873T (FARICIMAB).....1731
14875X (DROSPIRENONE).....264
14876Y (FOSLEVODOPA + FOSCARBIDOPA).....1572
14877B (USTEKINUMAB).....1299
14878C (USTEKINUMAB).....1305
14879D (USTEKINUMAB).....1283
14886L (FOSLEVODOPA + FOSCARBIDOPA).....1573
14887M (FOSLEVODOPA + FOSCARBIDOPA).....1573
14890Q (USTEKINUMAB).....1298
14891R (USTEKINUMAB).....1319
14892T (USTEKINUMAB).....1291
14893W (USTEKINUMAB).....1313
14896B (FOSLEVODOPA + FOSCARBIDOPA).....1573
14897C (USTEKINUMAB).....1283
14898D (USTEKINUMAB).....1276
14899E (USTEKINUMAB).....1313
14907N (USTEKINUMAB).....1316
14908P (USTEKINUMAB).....1307
14909Q (USTEKINUMAB).....1301
14916C (USTEKINUMAB).....1341
14917D (USTEKINUMAB).....1310
14918E (USTEKINUMAB).....1302
14926N (USTEKINUMAB).....1301
14933Y (USTEKINUMAB).....1305
14934B (USTEKINUMAB).....1276
14935C (USTEKINUMAB).....1291
14941J (DROSPIRENONE + ETHINYLESTRADIOL).....263
14943L (USTEKINUMAB).....1319
14944M (USTEKINUMAB).....1309
14954C (DROSPIRENONE + ETHINYLESTRADIOL).....263
14955D (SECUKINUMAB).....1194
14956E (SECUKINUMAB).....1165
14957F (SECUKINUMAB).....1180
14958G (ADALIMUMAB).....774
14966Q (PALOVAROTENE).....1496
14967R (PALOVAROTENE).....1497
14968T (PALOVAROTENE).....1496
14969W (RIVAROXABAN).....149
14970X (SECUKINUMAB).....1174
14971Y (SECUKINUMAB).....1170

14972B (SECUKINUMAB).....1190
14973C (ADALIMUMAB).....777
14975E (ADALIMUMAB).....664
14976F (ADALIMUMAB).....664
14979J (DUPILUMAB).....257
14980K (PALOVAROTENE).....1496
14981L (PALOVAROTENE).....1497
14982M (PALOVAROTENE).....1497
14983N (SECUKINUMAB).....1166
14985Q (ADALIMUMAB).....651
14989X (PALOVAROTENE).....1497
14990Y (RUXOLITINIB).....438
14991B (RUXOLITINIB).....439
14992C (PEGINTERFERON ALFA-2A).....534
14994E (RIVAROXABAN).....151
14995F (ADALIMUMAB).....746
14996G (ADALIMUMAB).....717
14997H (ADALIMUMAB).....807
14998J (ADALIMUMAB).....807
1499X (HYDROCORTISONE).....292
15001M (DENOSUMAB).....1489
15002N (RUXOLITINIB).....439
15004Q (SECUKINUMAB).....1197
15005R (ADALIMUMAB).....809
15006T (ADALIMUMAB).....780
15007W (ADALIMUMAB).....774
15008X (ADALIMUMAB).....783
15009Y (ADALIMUMAB).....783
1500Y (HYDROCORTISONE).....292
15010B (ADALIMUMAB).....657
15013E (DENOSUMAB).....1489
15014F (RUXOLITINIB).....439
15017J (RIVAROXABAN).....150
15018K (SECUKINUMAB).....1182
15019L (ADALIMUMAB).....777
1501B (HYDROCORTISONE SODIUM SUCCINATE)...293
15020M (ADALIMUMAB).....657
15023Q (PALOVAROTENE).....1496
15027X (SECUKINUMAB).....1171
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15029B (SECUKINUMAB).....1167
15030C (SECUKINUMAB).....1200
15031D (ADALIMUMAB).....651
15035H (DUPILUMAB).....254
15037K (RIVAROXABAN).....148
15038L (ADALIMUMAB).....780
15039M (ADALIMUMAB).....809
15045W (PEGINTERFERON ALFA-2A).....533
15047Y (FAMOTIDINE).....20
15048B (TIMOLOL).....1714
15049C (CAPIVASERTIB).....456
1504E (NIZATIDINE).....21
15050D (ETANERCEPT).....935
15051E (TRAMETINIB).....417
15052F (LUMASIRAN).....127
15054H (ESTETROL + DROSPIRENONE).....263
15055J (DABRAFENIB).....402
15056K (DABRAFENIB).....402
15057L (TRAMETINIB).....417
15058M (BENZATHINE BENZYLPENICILLIN).....312
15059N (CAPIVASERTIB).....456
1505F (NIZATIDINE).....21
15060P (LUMASIRAN).....128
15061Q (FAMOTIDINE).....21
15062R (TIMOLOL).....1713
15063T (BENZATHINE BENZYLPENICILLIN).....312
15064W (IPTACOPAN).....1463
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15074J (ETONOGESTREL + ETHINYLESTRADIOL)....259
15082T (DARATUMUMAB).....484
15087C (PALOVAROTENE).....1497
15088D (DARATUMUMAB).....485
15089E (ELAFIBRANOR).....58
15097N (BREXPIPRAZOLE).....1597
1509K (DEXTRAN-70 + HYPROMELLOSE).....1741
15107D (ELAFIBRANOR).....59
1510L (HYDROCORTISONE SODIUM SUCCINATE)...293
15110G (BIMEKIZUMAB).....1077
15112J (BIMEKIZUMAB).....1085
15114L (CABOZANTINIB).....452
15115M (CABOZANTINIB).....452
15116N (BIMEKIZUMAB).....1091
15118Q (APOMORPHINE).....1579
15119R (BIMEKIZUMAB).....1077
1511M (HYDROCORTISONE SODIUM SUCCINATE)..293
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15122X (ARIPIPRAZOLE).....1597
15123Y (CABOZANTINIB).....453
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15128F (ARIPIPRAZOLE).....1597
15129G (CABOZANTINIB).....453
1512N (HYDROXYCHLOROQUINE).....1477
15130H (CABOZANTINIB).....452
15131J (BIMEKIZUMAB).....1091
15133L (BIMEKIZUMAB).....1085
15134M (ODEVIXIBAT).....60
15135N (ODEVIXIBAT).....62
15136P (ODEVIXIBAT).....63
15137Q (ADALIMUMAB).....728
15146E (ADALIMUMAB).....826
15147F (ADALIMUMAB).....729
15148G (ADALIMUMAB).....549
15149H (ADALIMUMAB).....730
15150J (ODEVIXIBAT).....63
15151K (ODEVIXIBAT).....64
15152L (TERIPARATIDE).....305, 1495
15153M (ADALIMUMAB).....704
15155P (ADALIMUMAB).....549
15157R (ODEVIXIBAT).....66
15158T (ODEVIXIBAT).....64
15159W (ADALIMUMAB).....729
1515R (GLYCERYL TRINITRATE).....165
15160X (ADALIMUMAB).....704
15161Y (ADALIMUMAB).....828
15162B (ADALIMUMAB).....705
15163C (ODEVIXIBAT).....67
15164D (ODEVIXIBAT).....63
15165E (ODEVIXIBAT).....64
15166F (ODEVIXIBAT).....66
15167G (ODEVIXIBAT).....67
15168H (DAPSONE).....258, 342
1516T (GLYCERYL TRINITRATE).....165
15170K (ADALIMUMAB).....728
15172M (ADALIMUMAB).....751
15174P (ODEVIXIBAT).....63
15180Y (ADALIMUMAB).....730
15181B (ODEVIXIBAT).....62
15182C (ODEVIXIBAT).....62
15183D (ODEVIXIBAT).....62
15184E (ODEVIXIBAT).....60
15185F (ODEVIXIBAT).....60
15186G (ODEVIXIBAT).....66
15188J (TERIPARATIDE).....304, 1494
15189K (ADALIMUMAB).....704
15190L (ADALIMUMAB).....751
15192N (ODEVIXIBAT).....67
15193P (ODEVIXIBAT).....67
15194Q (ODEVIXIBAT).....60
15195R (ODEVIXIBAT).....64
15196T (ODEVIXIBAT).....66

15199Y (PRAZIQUANTEL).....1653
15200B (ADALIMUMAB).....826
15201C (ADALIMUMAB).....828
15203E (CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE).....240
15206H (AFLIBERCEPT).....1722
15207J (AFLIBERCEPT).....1727
15209L (ABIRATERONE (&) PREDNISOLONE).....532
15212P (CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE).....241
15213Q (AFLIBERCEPT).....1723
15214R (AFLIBERCEPT).....1725
15215T (AFLIBERCEPT).....1719
15217X (AFLIBERCEPT).....1724
15218Y (AFLIBERCEPT).....1718
15219B (AFLIBERCEPT).....1718
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15220C (AFLIBERCEPT).....1721
15221D (AFLIBERCEPT).....1719
15222E (PIOGLITAZONE).....106
15223F (PIOGLITAZONE).....106
15229M (PIOGLITAZONE).....107
15232Q (BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM).....1682
15233R (BUDESONIDE + FORMOTEROL).....1671
15236X (PIOGLITAZONE).....106
15239C (PRAZIQUANTEL).....1653
15240D (BUDESONIDE + FORMOTEROL).....1663
15241E (IVABRADINE).....169
15242F (PROPYLENE GLYCOL).....1746
15243G (BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM).....1681
15248M (AFLIBERCEPT).....1721
15252R (EMPAGLIFLOZIN).....122
15253T (EMPAGLIFLOZIN).....120
15256Y (BIMEKIZUMAB).....1076
15257B (DAPAGLIFLOZIN).....116
15260E (AFLIBERCEPT).....1720
15261F (PIOGLITAZONE).....106
15262G (BIMEKIZUMAB).....1088
15267M (PIOGLITAZONE).....106
15268N (OPICAPONE).....1588
1526H (FLUCLOXACILLIN).....315
15270Q (IVABRADINE).....168
15272T (POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL).....1745
15278D (FEDRATINIB).....432
15279E (FEDRATINIB).....431
1527J (FLUCLOXACILLIN).....315
15280F (REPOTRECTINIB).....472
15282H (DESMOPRESSIN).....284
15288P (REPOTRECTINIB).....473
15289Q (GIVOSIRAN).....127
15291T (DESMOPRESSIN).....286
15293X (ELRANATAMAB).....491
15295B (GARADACIMAB).....155
15300G (ELRANATAMAB).....492
15305M (GARADACIMAB).....155
15311W (SEMAGLUTIDE).....114
15312X (DESMOPRESSIN).....287
15313Y (DESMOPRESSIN).....287
15317E (GARADACIMAB).....157
1531N (INSULIN NEUTRAL HUMAN).....87
15320H (POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL).....1745
15322K (SEMAGLUTIDE).....114
15323L (DESMOPRESSIN).....288
15326P (POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL).....1745
15332Y (GARADACIMAB).....156
15333B (DESMOPRESSIN).....286
15336E (FRUQUINTINIB).....440
15337F (GLYCOPYRRONIUM).....252
15338G (LAMOTRIGINE).....1562
15339H (LAMOTRIGINE).....1563
1533Q (INSULIN ISOPHANE HUMAN).....87
15340J (LAMOTRIGINE).....1563
15341K (LAMOTRIGINE).....1562
15342L (LAMOTRIGINE).....1563
15343M (LAMOTRIGINE).....1562
15344N (FRUQUINTINIB).....440
15345P (CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE).....241
15346Q (LAMOTRIGINE).....1563
15348T (SALBUTAMOL).....1657
15349W (LAMOTRIGINE).....1562
15350X (LAMOTRIGINE).....1562
15351Y (LAMOTRIGINE).....1563
15352B (CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE).....240
15353C (DAPAGLIFLOZIN).....118
15354D (ACALABRUTINIB).....442
15355E (ADRENALINE (EPINEPHRINE)).....165, 1700
15356F (ACALABRUTINIB).....443
15357G (VENETOCLAX).....513
15358H (VENETOCLAX).....514
15359J (ADRENALINE (EPINEPHRINE)).....164, 1699
15360K (ACALABRUTINIB).....444
15361L (VENETOCLAX).....515
15365Q (BENZATHINE BENZYLPENICILLIN).....312
15366R (TENOFOVIR DISOPROXIL + EMTRICITABINE).....354
15368W (USTEKINUMAB).....1299
15371B (SELPERCATINIB).....475
15376G (ALECTINIB).....408
15377H (METHADONE).....1526
15378J (OSIMERTINIB).....401
15380L (TRIGLYCERIDES MEDIUM CHAIN FORMULA).....1768
15381M (MIDAZOLAM).....1606
15382N (UPADACITINIB).....1448
15383P (TENOFOVIR DISOPROXIL + EMTRICITABINE).....354
15388X (MIDAZOLAM).....1606
15389Y (BENZATHINE BENZYLPENICILLIN).....312
15390B (USTEKINUMAB).....1305
15392D (OSIMERTINIB).....401
15393E (INSULIN DEGLUDEC).....88
15397J (USTEKINUMAB).....1301
15400M (USTEKINUMAB).....1310
15401N (FUTIBATINIB).....452
15404R (ADRENALINE (EPINEPHRINE)).....163, 1698
15410C (TENOFOVIR DISOPROXIL + EMTRICITABINE).....354
15414G (ADRENALINE (EPINEPHRINE)).....163, 1698
15415H (PHENOBARBITAL).....1544
15416J (SELPERCATINIB).....475
15421P (TOCILIZUMAB).....1231
15423R (OXYCODONE).....1517
15424T (OXYCODONE).....1518
1542E (IPRATROPIUM).....1693
15432F (TOCILIZUMAB).....1233
15436K (ABALOPARATIDE).....302
15437L (VORASIDENIB).....509
15441Q (TOCILIZUMAB).....1251
15444W (TOCILIZUMAB).....1229
15445X (TOCILIZUMAB).....1264
15446Y (TOCILIZUMAB).....1243

15447B (SELPERCATINIB).....474
15448C (TILDRAKIZUMAB).....1209
15449D (TILDRAKIZUMAB).....1212
15450E (OXYCODONE).....1517
15454J (TOCILIZUMAB).....1233
15456L (TOCILIZUMAB).....1229
15457M (TOCILIZUMAB).....1231
15458N (TILDRAKIZUMAB).....1214
1545H (AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES).....1760
15461R (VORASIDENIB).....509
15462T (TOCILIZUMAB).....1251
15468D (ABALOPARATIDE).....303
1546J (AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE).....1783
1547K (AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE).....1782
1548L (AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE).....1780
15491H (TOCILIZUMAB).....1264
15492J (TOCILIZUMAB).....1243
15494L (SELPERCATINIB).....475
15495M (OXYCODONE).....1517
15506D (BENZATHINE BENZYLPENICILLIN).....312
15507E (ESTRADIOL).....272
15517Q (DAPSONE).....258, 342
15521X (DISOPYRAMIDE).....160
15524C (ESTRADIOL).....272
15527F (BENZATHINE BENZYLPENICILLIN).....312
15536Q (GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE).....1788
15539W (ADALIMUMAB).....703
15541Y (CICLOSPORIN).....1741
15542B (TACROLIMUS).....258
15548H (ADALIMUMAB).....751
1554T (ISONIAZID).....342
15550K (ADALIMUMAB).....807
15557T (ADALIMUMAB).....683
15558W (ADALIMUMAB).....809
1555W (ACICLOVIR).....343
15560Y (ALBENDAZOLE).....1653
15563D (ADALIMUMAB).....702
15564E (ADALIMUMAB).....802
15565F (ADALIMUMAB).....803
15566G (ADALIMUMAB).....730
15567H (ADALIMUMAB).....746
15572N (ADALIMUMAB).....549
15573P (ADALIMUMAB).....664
15575R (ADALIMUMAB).....717
15583E (ADALIMUMAB).....726
15584F (ADALIMUMAB).....637
1558B (ISOSORBIDE MONONITRATE).....166
15590M (ADALIMUMAB).....720
15591N (ADALIMUMAB).....632
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1561E (CLOMIPRAMINE).....1610
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1594X (ONDANSETRON).....51
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1598D (MERCAPTOPURINE).....358
1609Q (METHADONE).....1526
1611T (MESALAZINE).....81
1614Y (NAPROXEN).....1474
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1629R (METHYLDOPA).....172
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1644M (MORPHINE).....1515
1645N (MORPHINE).....1507
1646P (MORPHINE).....1509
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1654C (MORPHINE).....1511
1655D (MORPHINE).....1511
1656E (MORPHINE).....1511
1658G (NAPROXEN).....1475
1663M (ESTRADIOL).....270
1664N (ESTRADIOL).....270
1674D (NAPROXEN).....1474
1692C (NITROFURANTOIN).....334
1693D (NITROFURANTOIN).....335
1696G (NYSTATIN).....75
1699K (NYSTATIN).....75
1703P (PHENOXYMETHYLPENICILLIN).....314
1705R (PHENOXYMETHYLPENICILLIN).....314
1706T (CARBAMAZEPINE).....1548
1724R (CARBAMAZEPINE).....1548
1728Y (OLSALAZINE).....85
1746X (PARACETAMOL).....1537
1754H (PARAFFIN).....1744
1760P (ROXITHROMYCIN).....327
1761Q (INSULIN ISOPHANE HUMAN).....87
1762R (INSULIN NEUTRAL HUMAN).....87
1763T (INSULIN NEUTRAL HUMAN + INSULIN ISOPHANE HUMAN).....88
1770E (PARACETAMOL).....1537
1771F (ESTRIOL).....272
1775K (BENZYLPENICILLIN).....313
1779P (DANTROLENE).....1478
1781R (ESTRIOL).....272
1783W (CEFTRIAXONE).....324
1787C (PHENOXYMETHYLPENICILLIN).....313
1789E (PHENOXYMETHYLPENICILLIN).....313
1795L (NAPROXEN).....1475
1797N (CEFAZOLIN).....322
1799Q (CEFAZOLIN).....321
1801T (METFORMIN).....89
1805B (CLONAZEPAM).....1547
1806C (CLONAZEPAM).....1546
1807D (CLONAZEPAM).....1546
1808E (CLONAZEPAM).....1546
1810G (FUROSEMIDE).....175
1822X (PERHEXILINE).....167
1824B (MEFENAMIC ACID).....1476
1834M (GABAPENTIN).....1555
1835N (GABAPENTIN).....1555
1841X (POTASSIUM CHLORIDE).....124
1849H (SUMATRIPTAN).....1540
1850J (PHENOBARBITAL).....1544
1862B (PHENOXYBENZAMINE).....180, 282
1873N (PHENYTOIN).....1545
1874P (PHENYTOIN).....1545
1880Y (TAMOXIFEN).....522
1884E (AMOXICILLIN).....312
1886G (AMOXICILLIN).....310

1887H (AMOXICILLIN) ....310
1888J (AMOXICILLIN) ....310
1889K (AMOXICILLIN)....312
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1915T (MOMETASONE)....247
1916W (PREDNISOLONE)....293
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1934T (PREDNISONE)....294
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